

Philippine Performance Evaluation and Assessment Scheme
PPEAS for Newborn Screening Centers*

NSC Program Review 2017

Newborn Screening Reference Center
National Institutes of Health, UP Manila



** Based on the PEAS (version 8/25/06) developed by Health Resources and Services Administration, Maternal and Child Health Bureau, Genetic Services Branch, and National Newborn Screening and Genetics Resource Center, Department of Pediatrics, The University of Texas Health Science Center at San Antonio.*

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I. SERVICE DELIVERY

A. SPECIMEN COLLECTION - Proper specimen collection and information handling are essential to the screening process. Heel stick blood collection should be performed and blood collection device should meet the performance standards specified NSRC. Patient data/demographic information placed on the collection device should be complete, accurate and legible and the patient's identity and linkage to the specimen should be confirmed at the time of specimen collection. Many of the conditions in newborn screening require immediate diagnosis and treatment, and some of the testing procedures may be negatively affected by specimen collection/transport delays. Thus, the screening process must proceed quickly, accurately and efficiently in order to provide the greatest benefit.

	Indicators	Yes	No	In Progress	Remarks Manual Code /References
	Specimen Collection Device				
1.	Periodic checks of incoming cards document that 'out-of-date' devices/cards are not in use.				
2.	Distribution of the blood collection devices/cards includes an inventory control system that links serial numbers to submitters.				
3.	There is a procedure for specimen submitters to receive immediate replacement of defective/outdated collection devices/cards.				
	Specimen Collection/Transmittal				
1.	Written specimen collection procedures exist consistent with NSRC standard for blood collection on filter paper for newborn screening programs.				
	Specimen Receipt				
1.	There is an operational system at the screening laboratory for documenting:				
	a. Date of specimen receipt.				
	b. Time of specimen receipt.				
	c. "Unsatisfactory" specimens - including reason "unsatisfactory".				
2.	The laboratory quality assurance plan includes criteria for evaluating the specimen's acceptability for analysis at the time of laboratory receipt and check-in.				
3.	The defined specimen acceptability criteria include:				
	a. Quality indicators (e.g. no serum rings, no clots, etc.).				
	b. Analytical acceptability criteria regarding quantity of specimen.				
	c. Legibility of accompanying patient information printed in ALL CAPS.				
	d. Completeness of accompanying patient information (no blanks).				
	e. Accuracy of the accompanying patient information (name, dates, etc.)				
	f. Age of specimen.				
4.	There is a written procedure for rapid submitter notification of "unsatisfactory" specimens in addition to routine notification through a written (or electronic) laboratory report.				
5.	There is a written procedure for logging patient/specimen information.				
6.	All information logged are evaluated for correctness of data entry (where all data				

	fields cannot be monitored for staffing reasons, critical fields should be defined and their data quality monitored - possible methods include double entry or manual comparative checks).				
7.	Error rates for data entry are tracked and used to assess performance improvement.				
8.	There is a training plan for correcting poor data entry performance.				
9.	There is a process for updating missing critical data.				
10.	If data correction is allowed, there is a procedure for assuring that testing and reporting are not delayed while missing data are obtained.				
11.	Number of "unsatisfactory" specimens for each submitter are tracked daily including number of, and reasons for, "unsatisfactory" specimens in order to decrease the number of "unsatisfactory" specimens. (goal defined by program, generally <1%).				
12.	Number of invalid data fields <u>per specimen</u> data form are tracked daily including number of blank fields and obvious errors, in order to decrease the number of data errors.				
13.	Specimen submitters are periodically notified of their ongoing performance in submitting acceptable (valid) patient information.				
14.	There is a written procedure for improving submitter performance relative to quality of specimens submitted.				
15.	There is a written procedure for improving submitter performance relative to quality of the patient information submitted.				
16.	There is a system for documenting date, contacted person, and person contacting as part of the process for tracking the actions performed for "unsatisfactory" specimens.				
17.	There is a system for uniquely identifying specimens for laboratory tracking.				
18.	Specimens are processed and analyzed screened positive reported over time periods that comply with written procedures designed to optimize patient benefits (generally within 24 hours of specimen receipt).				
19.	Periodic audits are documented that assess the processing time and document any necessary corrective actions.				
	Specimen Tracking				
1.	A specimen tracking quality assurance plan exists to ensure that procedures for specimen receipt to the screening laboratory are properly followed				
2.	There is a time for acceptable specimen transmittal that is defined as part of the specimen tracking quality assurance plan (transmittal within 1 day is ideal; within 2-3 days is generally acceptable).				
3.	There is an audit mechanism for monitoring specimen transmittal times included in the specimen tracking quality assurance plan (audit should occur at least annually; preferably quarterly).				
4.	There is a procedure for periodically (at least annually) assessing and notifying				

	specimen submitters of their ongoing performance in timely submittal of specimens				
5.	There is a written procedure for corrective actions when a submitter is identified with a problem relative to timely specimen submittal (LATE)				
6.	A specimen tracking system is in place documenting:				
	a. If refusal of screening has occurred [date, person(s) refusing] (where allowed).				
	b. The reason(s) for refusal (if refusal occurred).				
	c. That every intensive care newborn receives a screening test by age 7 days.				
	d. That each specimen collected has been sent to the screening laboratory within 24 hours of collection.				
	e. That a screening result has been received for each submitted specimen within 7-14 days from the time it was sent to the laboratory.				
	f. That urgent screening results have been rapidly transmitted to newborn's care provider - for discussion (for action of NSRC)				
7.	There is a tracking system that can monitor specimen transport				
8.	There is a process for utilizing the tracking system				
9.	Where a courier system is used for specimen transport, records exist documenting:				
	a. The receipt of each blood specimen.				
	b. Whether or not the specimen was analytically acceptable.				
	c. The reason(s) for any specimens deemed unacceptable.				

B. TESTING PROCESS - The testing processes must undergo rigorous quality checks in order to ensure accurate screening results. Up-to-date procedure manuals are required, including relevant updates, and the laboratory must have a certificate for operation from the Department of Health. There must be an overall quality assurance plan with defined corrective actions to be taken when quality control indicators detect problems. Testing must be accurate and precise, and testing must occur within a time period sufficient to accomplish the goal of early detection and treatment as a preventive measure.

	Indicators	Yes	No	In Progress	Remarks
	Procedures Manual				
1.	There is laboratory procedure's manual(s).				
2.	The procedure's manual defines the process for establishing analytical ranges for the various screening tests				
3.	The procedure's manual(s) is updated as procedural changes occur.				
4.	All procedural changes are appropriately documented with date and person changing.				
5.	Discontinued procedures are archived with documentation of the date the procedure was begun, the date discontinued, and the person archiving.				
6.	There is a documented review of the procedure's manual(s) by the laboratory technical supervisor at least annually.				

7.	A working procedure's manual(s) is readily available to all technical personnel.				
8.	There is a written course of emergency action to be taken if a test system fails.				
9.	There is an accountability process that ensures that personnel follow the procedures included in the procedure's manual(s).				
	Quality Assurance Program				
1.	There is a designated quality assurance officer.				
2.	There is a written quality assurance plan for the laboratory.				
3.	There is a periodic review of the quality assurance plan.				
4.	There is routine documentation and review of all adverse quality assurance events.				
5.	The quality assurance plan defines a quality control process in the laboratory.				
6.	The quality assurance plan specifies a process for:				
	a. Documenting and sharing quality assessment findings among staff members in order to resolve problems.				
	b. Documenting corrective actions for any discrepancies found.				
	c. Documenting and reviewing the effectiveness of corrective actions taken with appropriate staff				
	d. Preventing recurrence of identified problems.				
	e. Obtaining information to assess clinical validity of screening tests.				
	f. Comparing screening test results with confirmatory testing results and resolving any discrepancies.				
7.	The methods for using quality control materials specify:				
	a. The number, type and frequency of testing controls for each different analytical procedure.				
	b. An identical analytical process for analysis of controls and patient's specimens.				
	c. Acceptability criteria with corrective actions if a test system is "out of control."				
	d. A protocol for detecting/correcting errors resulting from a test system failure.				
	e. A protocol for detecting/correcting errors caused by operator performance.				
	f. Documentation of corrective actions in the event of error detection.				
8.	The use of control materials complies including:				
	a. A procedure for validating the concentration of control materials.				
	b. A procedure for establishing acceptable accuracy limits for controls.				
	c. A procedure for establishing acceptable precision limits for controls.				
	d. A process for monitoring assay accuracy based on control results.				
	e. A process for monitoring assay precision based on control results.				

	f. Documentation of <i>corrective actions</i> in the event of accuracy or precision non-compliance.				
9.	Validation of assay calibrators/standards including:				
	a. A process for validating calibrator/standard concentrations before routine use.				
	b. A process for documenting all calibrator/standard validation activity.				
	c. A process for actions to be taken when performance of controls indicates a deviation from the anticipated results.				
	d. Criteria for establishing acceptable assay performance (linearity, CV, etc.)				
	e. A process for documenting acceptable assay performance.				
	f. A process for action(s) when assay performance is unacceptable.				
	g. Documentation of corrective actions when unacceptable assay performance is noted.				
10.	The use of commercial assay kits and kit components including:				
	a. A protocol for reagent kit validation (both accuracy and precision).				
	b. Documentation of kit validation prior to routine use.				
	c. Adherence to manufacturer's protocol and/or documentation of all deviations.				
	d. Documenting acceptable kit performance indicators on a routine basis.				
	e. Where appropriate, validating/documenting proper instrument operation.				
	f. Documenting comparative evaluations of new lots of kit components with lots currently in use				
11.	There is a procedure for validating reagent performance including:				
	a. Comparison to stated precision/accuracy specifications (commercial reagents).				
	b. Establishing performance specifications (prepared reagents).				
	c. Documenting performance characteristics.				
12.	The laboratory satisfactorily participates in dried blood spot external proficiency testing activities on a quarterly basis				
13.	There is a comprehensive written procedure for handling analysis, review and reporting of proficiency testing results.				
14.	The analytical procedure for analyzing proficiency and patient specimens is identical.				
15.	To the extent possible, proficiency samples are run for each analyte in the laboratory.				
16.	Personnel who routinely perform testing test proficiency specimens.				
17.	Proficiency testing records are accessible on site for at least two years.				
18.	There is a written procedure for investigating, documenting and correcting problems identified as a result of unacceptable proficiency testing results.				

19.	There is documentation of appropriate review of proficiency testing results by the technical laboratory supervisor.				
20.	There is documentation of corrective actions taken in the event of a proficiency testing error.				

C. SCREENING TEST RESULTS - Screening results must be accurate and reported in a timely way. A procedure must exist for immediate reporting of results considered to indicate the possibility of a clinical emergency, including documentation of reporting and report receipt. A procedure should exist for quickly reporting unsuitable specimens so that repeat testing can occur in a timely way.

	Indicators	Yes	No	In Progress	Remarks
	Laboratory Assay Documentation				
1.	Post-analytic quality control activities are included in the laboratory procedure's manual.				
2.	There is appropriate documentation of daily quality control results for each laboratory screening test.				
3.	There is appropriate (comparative) documentation of long-term quality control (i.e. across lots of reagents, etc.)				
4.	There is documentation of corrective action following a control failure.				
5.	There is documentation of assessing trends in patient results (median, means, etc.).				
6.	Assay quality control is reviewed and approved by a minimum of two qualified staff before results are released.				
7.	There is a documented audit trail (date, and personnel identification when recording:				
	a. Test results.				
	b. Quality control validation.				
	c. Assay completion and release.				
	d. Edits (if made).				
8.	There are periodic audits (at least quarterly) by the in-house quality assurance officer of all quality assurance documentation to assess overall analytical quality and verify that corrective actions have been successful				
	Laboratory Result Reporting				
1.	The system quality assurance plan addresses reporting of test results.				
2.	There is a written policy that defines the timely reporting for all testing that includes "in-range", "out-of-range", and invalid results (preferably all results have been reported within 7 days of specimen receipt; "invalid" specimens have been reported within 24 hours of receipt, "out-of-range" results have been reported as quickly as possible)				
3.	There is a process to audit whether a timely report has been generated for each specimen received (including "in-range", "out-of-range", and "invalid" reports).				
4.	There is a separate <u>reporting procedure</u> defined for cases of immediate follow-up				

	(including reporting protocol, information to be transmitted and documentation required).				
5.	There is a daily audit of analytical activity that evaluates testing status for all specimens to ensure that:				
6.	a. All specimens received (including previous days) are accounted for.				
7.	b. Any outstanding tests are scheduled for timely completion.				
8.	An efficient and effective system exists for transferring test results from the screening laboratory to the person(s) responsible for follow-up/tracking.				
9.	There is a predetermined time frame within which results requiring emergency follow-up are transmitted to the appropriate follow-up coordinator.				
10.	For telephone reporting of test results requiring immediate follow-up, there is documentation that includes name of person contacted, date, time, and by whom.				
11.	For telefax or other messaging of test results requiring immediate follow-up, there is documentation that results were sent including name of person sending.				
12.	There is an appropriate means (staff and process) for communicating urgent test results outside of usual working hours (weekends, holidays) when appropriate.				
13.	The result transfer process is periodically audited to ensure that it is timely and appropriately documented.				
14.	Sufficient patient information is included in the transmitted laboratory report to appropriately and accurately identify the patient.				
15.	The final laboratory report includes date of receipt, date of collection, accession and report run.				
16.	Numerical values are not reported when such value is outside of the analytical range (these must be reported as greater than highest standard or is lower than the lowest standard).				
17.	Expected results are given for each analyte or procedure reported.				
18.	There is a defined procedure for correcting reporting errors.				
19.	Corrections to reports are visibly noticeable (no correction tape).				
20.	An audit trail documents who, what, why and when report edits were made.				

D. MONITORING OF TIMELY AND UNIVERSAL SCREENING - In order for the newborn screening system to achieve the goal of early identification and intervention for affected newborns, a system must exist to ascertain the screening status of all newborns within the screening jurisdiction. This system must include linkage between birth certificates and newborn screening records. It must also include appropriate linkages between public and private screening systems.

Time element is based on RA 9288 definition which is after twenty-four (24) hours up to three (3) days from complete delivery of the newborn and seven (7) days of age for sick and premature babies.

	Indicators	Yes	No	In Progress	Remarks
	Initial Screenings				
1.	Compliance monitoring includes newborns born in:				

	a. Private hospital				
	b. DOH retained				
	c. Special government				
	d. LGU facilities				
	e. Private lying-in facilities				
	f. In a facility receiving services through other than the officially designated screening laboratory (ies). - incorporate to RO peas				
2.	Numbers and reasons for testing refusals are periodically reviewed to determine whether there are trends in refusals that require further investigation and action (pending revision of dissent form)				
	Repeat Screenings/Confirmatory Tests				
1.	A process exists for monitoring compliance with repeat test that may be necessary as a result of:				
	a. A required second screening specimen to confirm outside normal limits.				
	b. An initial test result requiring a second screening specimen as a result of inconsistent or inconclusive testing results.				
	c. An unsatisfactory initial screening test/no specimen.				

E. SHORT-TERM FOLLOW-UP - Short-term follow-up begins with a screening result that requires follow-up and ends with resolution of the screening results (i.e. newborn diagnosed and accessing appropriate intervention activities, newborn not affected, or newborn lost to follow-up). Screening results requiring follow-up include: (1) "invalid" - screening process could not be completed according to established criteria (unsuitable specimen or test, no specimen, or incomplete information), and (2) "Out-of-range" - any screening result outside of the expected range (elevated or deficient) of testing results established for a particular condition (includes carrier results and any findings indicating the need for further testing).

	Indicators	Yes	No	In Progress	Remarks
	Follow-up Procedures				
1.	A defined protocol exists for actively following/tracking specimens with screening results that are:				
	a. "outside normal limit."				
	b. "unsatisfactory."				
2.	All follow-up/tracking protocols for "out-of-range" or "invalid" screening test results should have a clearly defined:				
	a. Starting actions (e.g. telephone call or letter).				
	b. Monitoring actions (specimen monitoring, follow-up calls/letters, nurse visits etc.)				
	c. End points (when follow-up activities have exhausted all reasonable avenues of contact).				
3.	The follow-up protocols for each type of testing result (above) includes specifics for immediate notification of:				

	a. Newborn Screening Facilities (Specimen submitter)				
	b. RO NBS Coordinator				
	c. Parents/guardians.				
	d. Attending Physician (Primary care practitioner)				
4.	All documentation requirements for follow-up steps are clearly defined.				
5.	For "out-of-range" results, the notification process includes an urgent request for appropriate follow-up action, which may include requesting a repeat newborn screen, serum confirmatory testing, clinical evaluation, etc.				
6.	Specimens requested as a result of an "out-of-range" initial result (requiring a repeat heel stick specimen instead of serum confirmation) are closely monitored to ensure timely specimen receipt.				
7.	Other actions requested as a result of an "out-of-range" initial result, including serum testing, and clinical evaluation are monitored according to a time-line consistent with rapid resolution of all screening test results.				
8.	For unsatisfactory specimens, notifications include an urgent request for obtaining an immediate repeat specimen.				
9.	The unsatisfactory notifications include an explanation of the reason for the repeat request, including <u>why</u> a specimen may have been considered unsatisfactory.				
10.	Specimens requested as a result of an unsatisfactory initial submission are monitored to ensure timely specimen receipt.				
11.	Procedures for follow-up actions and activities exist in printed form (manual - may also be electronic) that include:				
	a. A permanent historical record of all procedural changes over time (i.e. permanent reference manual).				
	b. Documentation (date and signature) of annual review by the follow-up supervisor.				
	c. Documentation (date and initials) of procedural changes at the time changes were implemented.				
	d. Detailed follow-up/tracking protocols for each screened condition (flow charts).				
	e. A working copy readily available for employee use containing proper documentation of review and update.				
12.	The follow-up procedures manual is checked at least annually to ensure that the appropriate documented reviews/changes have occurred and that signatures, dates, and initials are in place.				
13.	The follow-up process includes a mechanism for direct communication with parents if other communications procedures fail.				
14.	The follow-up procedures include accumulating and recording summation data ("out-of-range" results tracked, number confirmed, number lost, time to diagnosis, etc.)				

15.	Appropriate follow-up data are reported to the NSRC database as quickly as possible.				
	Follow-up Communication				
1.	Written scripts are available for guidance where telephone contact is prescribed.				
2.	Letters used as part of follow-up are reviewed by appropriate advisors, consultants and parent recipients, and are found to be:				
	a. Consistent				
	b. Accurate				
	c. Brief, concise and easy to understand.				
	d. Informative.				
	e. Sensitive (firm but avoiding unnecessary alarm).				
	f. Of appropriate literacy level.				
3.	Concise, informative, next action steps are available for the health care professional.				
4.	Appropriate instructions accompany any letters sent to parents regarding testing results.				
5.	Adequate number of trained and qualified follow-up staff are available to accomplish required communications tasks with access to other sources of information should additional information be needed.				
6.	Protocols detail work coverage and communications that might be necessary outside of normal working hours (including weekends and holidays) as a result of available laboratory test results.				
7.	Documentation of communication processes conforms to the follow-up operations manual.				
8.	Documentation of communications concerning test results includes:				
	a. Date				
	b. Time				
	c. Type of communication				
	d. <u>Name</u> of person communicating the information				
	e. Name of person receiving the information				
	f. Explanatory notes				
9.	Documentation of follow-up endpoint/case disposition includes:				
	a. Final case disposition (confirmed, normal, lost to follow-up, expired)				
	b. Date evaluated to confirm screening results.				
	c. Date of diagnosis/case disposition.				
	d. Treatment/intervention date (if applicable).				
	e. Test results on which diagnosis was based.				
	f. <u>Name</u> of person communicating diagnosis information.				
	g. For “open cases”, clinical surveillance and action plan to achieve case resolution.				

	h. Identification of the person recording/entering the information.				
	i. For diagnosed cases (i.e. confirmed), referral information (e.g. sub-specialty provider, support services) and enrollment in early intervention, and long-term follow-up activities.				
	j. Documentation of timely endorsement to the continuity clinic exists.				

G. PROGRAM EVALUATION - In order to determine whether and how the goals of newborn screening are being met, and to refine and improve the newborn screening system, it is appropriate to periodically and continuously evaluate selected indicators. An Evaluation Plan should exist that clearly defines the selected indicators, assigns responsibility for their monitoring, and outlines the periodicity with which evaluations are to occur. Program evaluation should encompass both short-term and long-term activities.

	Indicators	Yes	No	In Progress	Remarks
	Short-Term Program Evaluation				
1.	The follow-up for evaluating the short-term follow-up process. Operations manual includes a plan.				
2.	As a part of the evaluation process for screening and short-term follow-up, there is:				
	a. A defined process for obtaining clinical feedback for each condition diagnosed.				
	b. A defined procedure for investigating and reconciling unexplained differences between screening results and clinical findings (updated for ENBS).				
	c. Documentation of the process steps for resolving significant differences between screening laboratory test results and confirmatory laboratory test results.				
	d. A periodic review of recall rates for each screened condition (within the program and in comparison to other programs) with the goal of decreasing recall without missing cases.				
	e. A periodic review of laboratory result trends (i.e. excessive "out-of-range" results, etc.) to aid in detecting analytical or other aberrations (e.g. kit problems, transport problems, etc.)				
	f. A plan for corrective action when adverse result reporting trends are identified (e.g. reassess kit calibrators, review collection/transmittal procedures).				
	g. A protocol for re-evaluating/confirming initial "normal" test results when an "outside normal limit" result on a subsequent specimen leads to a diagnosis				
	h. Ongoing review of initial test data when an "out-of-range" result on a subsequent specimen results in a confirmed diagnosis (including repeating the initial and subsequent tests in the same assay).				
	i. A protocol for resolving complaints received as a result of the follow-up				

	process.				
	j. A process for providing feedback to the screening laboratory when suspected conditions are confirmed.				
3.	The condition-specific data periodically evaluated include: (update to ENBS a-f)				
	a. The number of cases requiring follow-up for "out-of-range" results.				
	b. The number of confirmed cases (with appropriate biochemical/clinical back-up information).				
	c. The number of cases for which "out-of-range" test result follow-up could not be completed (with back-up information).				
	d. The number of cases requiring follow-up for an unsatisfactory specimen.				
	e. The time from birth to diagnosis and intervening steps (receipt at laboratory, result available, physician contacted).				
	f. Whether the case was diagnosed as a result of a second screen following an initial "normal" screening result.				
4.	The efficacy of the short-term follow-up system is periodically evaluated based on program data and refined as needed to improve overall follow-up activities.				

II. EDUCATION AND REGULATION

A. ADVOCACY PLAN - Advocacy and information dissemination is an essential element of the newborn screening system that must be present throughout. While educational activities exist in each of the three areas of screening activities (pre-analytical, analytical, and post-analytical), a comprehensive SMART (specific, measurable, achievable, realistic, time-bound -SMART) plan must exist so that education is implemented, utilized, and maintained throughout the system to meet the needs of public health professionals, health care providers, consumers, and policy-makers.

	Indicators	Yes	No	In Progress	Remarks
1.	A comprehensive, written education plan (inclusive of but not limited to communication and advocacy) prepared for the different stakeholders of the program exists based on NBS strategic framework. All materials should be reviewed by NSRC.				
2.	The comprehensive education plan provides information for:				
	a. Health professionals.				
	b. Health facilities.				
	c. LGUs (inclusive of LCEs, LHBs, ILHZ)				
	d. Consumers (Parents).				
	e. Program Partners (NGOs, Civic Grps, POs, etc)				
3.	The comprehensive education plan coordinated with NSRC and DOH includes:				
	a. Defined goals and objectives.				
	b. A means for obtaining input from stakeholders receiving the education.				

	c. A description of personnel necessary to administer all aspects of the plan.				
	d. Action steps to address the needs of each target audience.				
	e. Diverse modes of education (Internet, in-service, etc.).				
	f. A method for evaluating and ensuring cultural appropriateness.				
	g. A method for evaluating and ensuring appropriate literacy level.				
	h. Methods for disseminating materials to target audiences.				
	i. A method for periodic review and update of the plan.				
4.	Maintain a capacity for disseminating program updates				
5.	Copies of all pertinent laws, rules, and regulations are readily accessible within the program and are available to stakeholders.				
6.	The education plan (see previous bullet) has been submitted to newborn screening program administrators (NSRC and DOH) for review annually in order to assess its usefulness, its impact, and its relevance to current program activities, with updates as appropriate.				

B. PRENATAL EDUCATION - Education of parents and health professionals prior to the birth of the newborn provides the optimal mechanism for delivering useful information about the screening process. Materials should be available in a variety of formats and must meet the needs of the intended audience. They must be consistent with the general education plan and evaluated accordingly.

	Indicators	Yes	No	In Progress	Remarks
	Preparation / Distribution of PARENT/HEALTH CARE PROVIDER Education Materials				
1.	The parent/health care provider educational materials about newborn screening:				
	a. Adhere to the written educational plan.				
	b. Are accurate (as determined by appropriate subspecialty and/or other advisors).				
	c. Are current (reviewed/updated at least annually).				
	d. Are brief, concise, and easy to understand (as determined by parent users).				
	e. Are available in a variety of formats (e.g. brochure, video, lay publications, website, etc.).				
	f. Are sensitive to cultural issues (as determined by appropriate advisors).				
	g. Meet appropriate literacy standards (at least 4th grade or lower readability).				
	h. Are attractive and eye catching (as determined by parent users).				
	i. Meet their intended use (i.e. evaluated for impact by periodically assessing user knowledge).				
	j. Are available in appropriate languages.				
	k. Reflect national standards of practice, where national standards exist.				

	l. Are designed to meet the needs of the target audience (as determined by professionals using the materials)				
2.	Educational materials are distributed, to appropriate prenatal care providers as part of the educational plan. For NSRC review				
3.	Periodic assessment of availability occurs through random checks of distribution sites.				

C. PARENT EDUCATION - Short-Term Follow-Up

	Parent Education				
1.	Educational materials discussing screening results are available in compliance with the educational plan of the newborn screening program,				
2.	Health professionals, often representing the newborn's medical home, are provided with appropriate information to facilitate initial contact with parents about unsatisfactory or "out-of-range" test results with encouragement to present the information in an informative and sensitive way.				
3.	Access to a specialist is available to provide accurate information and support to the family [including face-to-face contact(s) if desired or needed].				
4.	Condition-specific action information is available and transmitted to healthcare practitioners along with "out-of-range" results.				

D. MARKETING / PROMOTIONS

	Indicators	Yes	No	In Progress	Remarks
	Client Inquiries and Feedback				
1.	A written protocol for handling inquiries exists.				
2.	A written protocol for handling requests for adding or changing information contained in patient records exists.				
3.	Records of record changes exist.				
	IEC/reference materials are available including:				
1.	RA 9288, IRR, and Presidential Proclamation				
2.	Manual of Operations				
3.	Posters				
4.	Audiovisual Presentations				
5.	Brochures				
6.	Facilitators Guidebook and factsheets				
7.	Flipcharts				
8.	Reviewed and approved innovations (IEC materials)				
9.	DOH, PhilHealth and DILG issuances				

III. HUMAN RESOURCE

HUMAN RESOURCE - Employee training must ensure qualified personnel for the appropriate tasks in the newborn screening laboratory and for follow-up activities. A comprehensive employee training program must exist and include new employee orientation, staff development, and performance assessment activities aimed at achieving a proficient workforce. A system for updating employee knowledge should exist along with a plan for cross-training wherever possible. Recruitment and retention of qualified workers should be a priority.

	Indicators	Yes	No	In Progress	Remarks
	Staffing				
1.	Sufficient staff are available to administer the program composed of:				
	a. Unit Head				
	b. Program Manager				
	c. Laboratory Manager				
	d. Technical Staff (at least 3)				
	e. Follow-up Head				
	f. Follow-up Nurse (at least 1)				
	g. IT specialist				
	h. Administrative Staff (at least 3)				
	i. Encoder/s (at least 1)				
2.	An organizational chart exists that includes pictures of employees and clearly identifies positions, lines of authority, and units involved in the implementation of the program <i>(include organizational chart as attachment)</i>				
3.	Written job descriptions exist that describe duties responsibilities, and performance expectations <i>(include written roles and responsibilities as attachment)</i>				
	Personnel Recruitment and Retention				
1.	A written policy for hiring, orientation and promotion exists for all levels of personnel.				
2.	Documentation exists demonstrating that employee competency has been assessed and approved prior to independent work assignments (update for ENBS).				
3.	A career advancement/retention plan/program exists.				
4.	Staff turnover is periodically monitored to assess the success of advancement /retention plan.				
5.	Written policies /processes on discipline, suspension, demotion and termination for all levels of personnel.				
6.	Procedures for handling internal complaints and accidents include:				
	a. A written protocol for handling internal complaints exists				
	b. A written protocol for handling laboratory accidents exists.				
	c. A record of complaints and accidents and their resolutions exists.				

7.	Personnel compensation plan meets or exceeds prescribed policies at the minimum				
	Personnel Competency				
1.	A written procedure, compatible with pertinent licensure requirements, is present to assess and document personnel competency.				
2.	Competency assessment includes:				
	a. Documentation of sufficient educational background.				
	b. Documentation of appropriate experience.				
	c. Documentation of local and international continuing education /certification.				
	d. Written procedures for actions to be taken when competency is deemed unacceptable.				
	e. Satisfactory performance on proficiency testing or other quality performance measures (e.g. certificate should be on file)				
	f. An annual assessment of technical competency using quantitative or semi-quantitative measures				
3.	Performance competency is evaluated at least annually for each employee. <i>(include personnel evaluation form as attachment)</i>				
	Continuing Program for Staff Development and Training				
1.	A program for continuing education on staff development and training exists. <i>(include outline of training plans attachment)</i> .				
2.	The training plan for new personnel includes (in writing) instruction in:				
	a. Administrative policies and procedures.				
	b. Program operation (including all systems components).				
	c. Safety.				
	d. Technical procedures (as appropriate).				
	e. Available resources (local, regional, national, international). (move to training)				
	f. Continuing education (move to training)				
3.	Updated training is documented. <i>(include proof of training (i.e., certificates, memos, written reports, budgetary allocations, etc.) as attachments)</i>				
4.	A plan for cross-training of personnel is present. Cross-training is an internal activity.				
5.	Cross-training (internal) activities are documented.				
6.	There is a process in place to obtain feedback from personnel (managers and trainees) concerning any internal training.				

IV. TECHNICAL STANDARDS

A. LABORATORY FORMS/RECORDS - There shall be a system of communication, reporting and recording of results of tests performed.

	Indicators	Yes	No	In Progress	Remarks
1.	Individual laboratory result forms bear the name of the authorized person responsible for the reliability of the results.				
2.	Procedures exist for reporting of work load, quality control, inventory control, etc.				
3.	Documentation exists for reports of work load, quality control, inventory control, etc.				
4.	A procedure exists for reports and analysis of incidents, adverse events, etc.				
5.	Documentation exists for reports and analysis of incidents, adverse events, etc.				
6.	The retention of laboratory records follows standards promulgated by the DOH and/or competent professional organizations.				
7.	Documentation exists for the retention of records that follows standards promulgated by the NAP/DOH.				
8.	A summary form for reporting normal, elevated and unsatisfactory sample results is in use. Minimum data fields:				
	a. Name of patient				
	b. Date of birth				
	c. Date of collection				
	d. Hospital of birth				
	e. Hospital of collection				
	f. Attending physician				
	g. Laboratory accession number				
	h. Result/Comment				
9.	Minutes of laboratory staff meetings document discussions of specimen collection, timeliness and quality of sample collection among others				

B. LABORATORY INSTRUMENTATION - Laboratory instruments must be properly calibrated and maintained in order to provide the highest quality testing. Proper and timely maintenance and calibration must be documented. Instrument calibration processes must be efficient, effective, and timely. A procedure should exist for linking specimen results to the instrument(s) used in cases where instrument operation is critical to the overall analytical process.

	Indicators	Yes	No	In Progress	Remarks
	Instrument Operation				
1.	There is a written operations procedure defining proper instrument operation.				
2.	The operations manual follows manufacturer's guidelines, or validated alternative protocol(s), for instrument use.				
3.	Appropriate training is documented for all instrument operators.				
4.	Where available, appropriate security controls exist that limit instrument access to properly trained personnel.				
	Quality Assurance				

1.	Instrument operation's checks (calibration/calibration) and include written procedures for:				
	a. Instrument calibration.				
	b. Validating proper instrument operation prior to use.				
	c. Validating proper instrument operation during analytical runs.				
	d. Documenting compliance with manufacturer's operations procedures				
	e. Documenting routine preventive maintenance and repairs.				
	f. Documenting corrective actions when operational problems are detected.				
	g. Documenting appropriate competency of instrument operators.				
	h. Documenting recalibration when necessary.				
	i. Re-verifying operational parameters when reagent lots change.				
	j. Re-verifying operational parameters when control lots change.				
	k. Re-verifying operational parameters when critical parts are replaced.				
	l. Re-verifying operational parameters when control materials reflect unusual analytical trends or shifts.				
	m. Re-verifying operational parameters when an instrument is moved				
	n. Documenting all reverification activities.				
2.	There are written maintenance protocols to ensure accurate and reliable testing performance of all laboratory instrumentation.				
3.	Manufacturer's guidelines for proper maintenance are followed.				
4.	Scheduled maintenance is performed with at least the frequency specified by the manufacturer.				
5.	The prescribed maintenance is documented for all laboratory equipment (including ancillary equipment such as incubators, centrifuges, refrigerators, etc.).				
6.	Corrective actions relative to functional problems are documented and include supervisory review.				

C. LABORATORY EQUIPMENT- The facility should contain adequate equipment in good working order.

	Indicators	Yes	No	In Progress	Remarks
1.	Laboratory instruments are in good condition to perform the required tests including:				
	a. MS/MS				
	b. HPLC				
	c. Victor 2				
	d. Autodelfia				
	e. Punchers etc.				
	f. Any other instruments (Please identify in Remarks)				
2	Refrigerator/Freezer is in good working condition.				

1.	A daily temperature record is posted on each refrigerator/freezer.				
2.	Food is not stored in reagent refrigerators.				
3.	Maintenance records exist for all equipment.				
4.	Manual/automated puncher is in good working condition.				
5.	Daily, weekly, monthly maintenance records exist and are posted on or near automated puncher.				
6.	Database system is operational and is compliant with NSRC recommendation.				
7.	Appropriate information system maintenance records exist.				
8.	A documented daily system of three-layer back-up is in place (e.g. NSC, host, and outside) in compliance with NSRC recommendation.				
9.	Program for calibration, preventive maintenance and repair for the equipment				
10.	Record of schedule of calibration and maintenance of equipment				
11.	Record of reports of preventive maintenance and repair				
12.	Contingency plan in case of equipment breakdown				
13.	Documented contingency plan in case of equipment breakdown				

D. LABORATORY SUPPLIES/REAGENTS - Supplies/reagents must be of appropriate quality to provide analytical integrity. Procedures must exist for assuring that supplies/reagents are fresh. Reagent concentrations should be validated prior to use with patient specimens. Records of lot numbers of date-sensitive reagents and supplies should exist and be linked to specimens analyzed.

	Indicators	Yes	No	In Progress	Remarks
	Quantity				
1.	There are updated inventory records of the status of all consumable supplies.				
2.	There are written procedures defining minimum inventory levels for all laboratory consumables.				
3.	Sources for consumable are given in the laboratory operation's manual.				
4.	Inventory is rotated to optimize use of materials with shorter expiration dates.				
5.	The shelf life of consumables is included in inventory considerations.				
6.	A periodic audit of consumables is performed to validate inventory records and supply use.				
	Quality				
7.	Supplies and reagents are stored according to manufacturer's recommendations.				
8.	Temperature monitoring records exist.				
9.	Appropriate storage area/technique for flammable, combustible and hazardous chemicals/reagents				
10.	Records of received consumable include date received, lot number and expiration date.				
11.	Reagent containers are properly labeled with:				
	a. Identification of contents.				
	b. Concentration.				

	c. Storage requirements.				
	d. Preparation Date.				
	e. Expiration date.				
	f. Preparer's initials. (Initials should link to a name in a reference document).				
	g. A document containing names and initials exists for proper linkage.				
	h. Lot number (if available).				
12.	There is appropriate documentation of safe disposal of expired reagents/supplies.				
13.	There is documentation of periodic inspections/corrective actions to ensure compliance with labeling and storage condition requirements.				
14.	Material Safety Datasheet (MSDS) available for all reagents/supplies and accessible to all personnel at all times				

E. WORKING ENVIRONMENT - Laboratory environmental conditions (e.g. temperature, humidity, etc.) must meet requirements for optimal assay performance. A written protocol should exist for monitoring conditions known to affect assay performance and instrumentation, and compliance should be documented.

	Indicators	Yes	No	In Progress	Remarks
	Quantity				
1.	Where appropriate, there are written criteria for acceptable environmental conditions.				
2.	Environmental conditions present meet manufacturer's recommended criteria for appropriate instrument operation				
3.	There are written procedures for correcting identified environmental problems.				
4.	There is appropriate and timely documentation of critical environmental variables.				
5.	Corrective actions are documented.				
6.	Space considerations meet appropriate standards for the working environment				
7.	Hallways and access areas are unobstructed.				
8.	A procedure is in place that alerts appropriate personnel of service/maintenance activities that might impact laboratory testing processes (e.g. janitorial services, exterminators, painters, air conditioning maintenance, etc.).				
9.	Sanitary procedure of the facility are in or exceeding compliance with the building code.(e.g. no. of toilets per number of personnel-male/female)				

F. LABORATORY SAFETY - Employee safety is an essential component in the newborn screening laboratory. A comprehensive safety training program must exist and successful completion by employees must be documented. Safety training must be timely and a mechanism for periodic updating of safety knowledge for employees must exist.

	Indicators	Yes	No	In Progress	Remarks
	Employee Training				

1.	Safety training is provided for all laboratory employees.				
2.	Training in precautions with blood borne pathogens is provided for all employees.				
3.	Training in precautions for using hazardous chemicals is provided for all employees.				
4.	All safety training is documented and records maintained.				
5.	Fire/bomb/natural disaster evacuation drills are conducted at least twice/year.				
6.	First aid and CPR training is available annually.				
	Safety Program				
1.	A defined laboratory safety program exists.				
2.	Safety oversight is the responsibility of a designated Safety Officer.				
3.	Where staffing permits, an active Safety Committee exists.				
4.	Comprehensive written safety procedures exist either as a separate manual or as a part of laboratory operations procedures				
5.	Documented review of the safety procedures occurs at least annually by the Safety Officer and the Newborn Screening Laboratory Manager				
6.	The written safety procedures include:				
	a. Defined authority for safety oversight.				
	b. Defined awareness responsibilities for individual employees.				
	c. General laboratory safety requirements (including illness and accident prevention.				
	d. Emergency response procedures in case of employee illness.				
	e. Emergency response procedures in case of a laboratory accident.				
	f. Proper procedures for handling blood borne pathogens.				
	g. Emergency responses in case of blood borne pathogen exposure.				
	h. Proper procedures for handling hazardous chemicals (chemical hygiene).				
	i. Emergency responses in case of hazardous chemical exposure				
	j. Fire prevention/control.				
	k. Emergency evacuation procedures for fire or other emergency.				
	l. Usage procedures for eye washes.				
	m. Usage procedures for emergency showers.				
	n. Avoidance of electrical hazards.				
	o. Emergency response in case of electrical shock.				
	p. Incident/accident reporting.				
7.	A comprehensive safety inspection occurs at least annually.				
8.	Periodic emergency evacuation drills occur at least twice annually.				
9.	Periodic reviews and staff discussions of all incidents/accidents are documented.				
10.	Updated Material Safety Data Sheets (MSDS) are readily accessible to all staff.				
11.	A written blood borne pathogen exposure control plan exists.				
12.	The blood borne exposure control plan is reviewed and updated annually.				

13.	Employees review the exposure plan at least annually (documented).			
14.	The exposure plan includes information on:			
	a. Program management.			
	b. Employee responsibility.			
	c. Universal precautions.			
	d. Needles and sharp object injuries.			
	e. Work area restrictions.			
	f. Specimens and specimen containers.			
	g. Contaminated equipment.			
	h. Personal protective equipment.			
	i. Regulated waste disposal.			
	j. Housekeeping.			
	k. Immunizations.			
	l. Post-exposure evaluation and follow-up.			
	m. Posted labels and warning and identification signs.			
	n. Biological Safety Cabinets in good working condition.			
15.	The blood borne pathogens exposure control plan is reviewed by the Safety Officer and the Newborn Screening Laboratory Manager at least annually.			
16.	A written chemical safety plan exists.			
17.	The chemical safety plan is reviewed and updated annually.			
18.	Employees review chemical safety plan at least annually (documented).			
19.	The plan includes information on:			
	a. Safety showers - location and use.			
	b. Safety eye washes - location and use.			
	c. Material Safety Data Sheets (MSDS).			
	d. Chemical storage - inventory procedure and storage precautions.			
	e. Reagent labeling.			
	f. Accident prevention.			
	g. Chemical waste removal and disposal.			
	h. Housekeeping (restricted or designated access).			
	i. Exposures, injuries and illnesses- immediate actions.			
	j. Medical consultations and examinations.			
	k. Emergency Response			
20.	The chemical safety plan is reviewed by the Safety Officer and the Newborn Screening Laboratory Manager			

V. ADMINISTRATION AND FINANCING

A. PROGRAM ADMINISTRATION AND FINANCING - In order for the newborn screening system to function, there are critical administrative and financial issues that must be addressed such as adequate newborn screening program staffing, system oversight capacity, and involvement of stakeholders in addressing system needs. Financing and administrative considerations must comprehensively address system needs for future growth.

	Indicators	Yes	No	In Progress	Remarks
	Administration				
1.	Mission, Vision and Objectives exist in accordance with RA 9288 “Newborn Screening Act” and are understood by all personnel.				
2.	Policies and procedures exist that govern program administration.				
3.	Updated program office contact details (names and telephone information) are available to consumers and health care providers.				
4.	The internal advisory committee (within the host agency):				
	a. Meets at least annually to address program issues for both laboratory and follow-up.				
	b. Provides advice to program administrators on other issues of interest to the group.				
	Management/Staff Meetings				
1.	Documentation of staff meetings occurring at least once monthly or as needed including attendance records.				
2.	Minutes of the meeting exist and are properly filed.				
	Financing				
1.	A cost accounting process is in place that adheres to standard accounting procedures and documents <u>all</u> program costs.				
2.	A program finance/business plan is available that provides a comprehensive plan for a sustainable newborn screening program.				
3.	Annual operational plan for current year containing objectives, targets, activities (advocacy, training and monitoring), budget and fund source exists.				
4.	The financing plan adequately addresses:				
	a. Laboratory screening services.				
	b. Comprehensive follow-up and management services.				
	a. Provisions for confirmatory/diagnostic laboratory services				
	b. Provisions for confirmatory/diagnostic clinical services.				
	c. A mechanism for assessing adequacy of payment for medical management				
	d. A mechanism for identifying and overcoming barriers to payment for medical management				
	e. Subspecialty consultative services				
	f. <i>Confirmatory and treatment of indigents</i>				
	g. <i>Laboratory service and treatment for long term follow up patients</i>				
	h. Parent consultative meetings				

	i. Genetic counseling services				
	j. Nutritional counseling services				
	c. Comprehensive educational activities.				
	d. Employee continuing education.				
	e. Employee recruitment and retention.				
	f. Public relations activities.				
	g. Program/test development. (Laboratory)				
	h. Information system and data management				
	i. Program evaluation activities (e.g. short- and long-term outcome data).				
	j. Research				
	k. Contingencies and damages resulting from disasters and emergencies.				
	l. Provisions to assist other NSCs and NSRC in time of need.				

B. PLAN OF ACTION

	Indicators	Yes	No	In Progress	Remarks
1.	Accomplishment report for previous year including fund utilization				
2.	Documentation of monitoring conducted reflecting issues and concerns, findings/problem areas, recommendations, agreements, and follow-up				
3.	Documentation of planning and consultative meetings reflecting issues and concerns, agreements and action points				
4.	Annual quality assurance plan with documentation				

C. CONTINGENCY PLAN - Contingency planning is essential to ensure continuity of the newborn screening system in case of an emergency. The plan must include not only laboratory contingencies, but also contingencies for specimen collection and transport, record integrity, and follow-up/service activities.

	Indicators	Yes	No	In Progress	Remarks
	System Administration				
1.	The comprehensive contingency plan for minimizing interruption of newborn screening systems operations in cases where an emergency may exist developed with input from representative internal/external stakeholders, which includes:				
	a. Continued laboratory operation/service.				
	b. Continuation of follow-up services (including diagnostic need)				
2.	The contingency plan includes:				
	a. A chain of authority to operationalize the plan and alternative notification processes for initiating the contacts necessary for implementation (i.e. strategies for overcoming compromised communications).				
	b. A system for ensuring that all administrative, laboratory, follow-up records are appropriately protected and maintained.				

	c. Strategies to meet the needs of families being followed by the newborn screening program to avoid disruption of needed medical services such as access to medical formulas and foods, and medications.				
	d. A method for ensuring that all screened newborns receive laboratory test results and needed follow-up.				
3.	A system back-up plan exists such that data are not at risk for loss due to an unexpected emergency.				
4.	There is documentation that the contingency plan has been periodically reviewed and tested.				

VI. INFORMATION MANAGEMENT SYSTEM

A. INFORMATION SYSTEM

	Indicators	Yes	No	In Progress	Remarks
1.	Updated directory of all health facilities including lying ins, birthing facilities, indicating the name of the health facility NBS coordinator, contact details, and status of implementation (active/inactive) using NSRC categories. <i>(Directory of Health Facilities must be available upon request)</i>				
2.	Statistics in compliance with NSRC for:				
	a. Number of newborns screened				
	b. Positive screens				
	c. Confirmed positive				
	d. Lost to follow-up				
	e. Number of unsatisfactory samples				
	f. List of active health facilities indicating status of implementation (active/inactive)				
3.	Reporting system/tracking and frequency of reports exists				
4.	Directory of specialists for referral and case management with contact details and clinic hours				
5.	An IT operations manual is present and sufficient.				

B. COMPUTERIZED INFORMATION SYSTEM - A computerized information system is essential for managing the patient information that begins at the time of birth and continues throughout life. While newborn screening systems are particularly interested in limited information sufficient to identify and manage their associated newborn screening information, the ability of the system to interact or integrate with other systems is a critical consideration. Data linkages should take advantage of related systems with similar data needs so that the time, effort, and errors that can occur in a duplicative process are avoided.

	Indicators	Yes	No	In Progress	Remarks
	Scope				
1.	A comprehensive, written computerized information system exist				
2.	A designated data protection officer exists.				
3.	Inclusion of a data field for the newborn screening serial number (filter paper collection device/card) compliant with existing standards exists.				
4.	Security levels and procedures for computer access are defined and enforced.				
5.	The newborn screening information system provides for:				
	a. Capture/input of patient demographic information.				
	b. Capture/input of screening laboratory test results.				
	c. Comprehensive and ongoing patient follow-up case management (including automated generation of reminder notices to case manager).				
	d. Immediate notification of "out-of-range" test results to submitters, primary care physicians				
	e. Immediate notification of unsatisfactory test results to appropriate persons.				
	f. Notification of "normal" test results to appropriate persons within defined time frame.				
	g. Appropriate and accurate laboratory work lists.				
	h. Creation/printing/transmittal of screening laboratory reports to NSF's <u>and</u> primary care physicians.				
	i. Editing/correcting reports (archived and/or printed).				
	j. A library of NSF's with current address information.				
	k. A library of subspecialists				
	l. A library of treatment centers				
	m. Tracking of user access and edits.				
	n. Documentation of capability for linking multiple specimens on the same infant.				
	o. User-friendly access to appropriate information for national data reporting.				
	p. Appropriate management reports for laboratory and follow-up managers.				
	q. Capability to accept and transmit select information to other external data systems such as the national data system or other electronic medical records				

	Integrity				
1.	A comprehensive, written operations manual exists.				
	a. Documentation of an annual review/update of the manual exists.				
	b. A data system quality assurance plan is included in the manual.				
2.	Data are maintained in an acceptable, standardized format.				
3.	Records documenting data back-up activities are maintained.				
4.	The data system includes appropriate security measures that protect the privacy of the data in the system.				
5.	Timely technical support for computer problems is readily available.				
6.	A system maintenance plan exists				
7.	Appropriate system hardware maintenance is documented.				
8.	Appropriate system software maintenance (updates) is documented.				
9.	Safeguards are in place to preclude unauthorized computer access.				
10.	Procedures exist for validating timeliness, accuracy and completeness of all data entry (i.e. that computer data are the same as manual calculations).				
11.	There is a procedure for verifying that calculation formulas used by an automated system for calculating patient results are correct before reporting results.				
12.	A procedure is in place for verifying that data transferred from a laboratory instrument and reported by an automated reporting system are identical.				
13.	There is a procedure for correcting/documenting inaccurate data generated by a computerized reporting system.				

VII. LINKAGES

	Indicators	Yes	No	In Progress	Remarks
	Networking				
1.	Established network with LGUs and other stakeholders (OB, pedia, midwives and other health professionals) <i>(MOAs or written agreement with LGUs & others must be available upon request)</i>				
	a. Advocacy				
	b. Recall of patients				
	c. Financing				
2.	Referral system (written protocol)				

VIII. FACILITY MANAGEMENT

A. PHYSICAL FACILITY - Adequate facility shall be in place for the safe and efficient operation of the laboratory

	Indicators	Yes	No	In Progress	Remarks
	Laboratory Facilities				

1.	Proper ventilation is in good working condition				
2.	Exhaust fan is in good working condition				
3.	Adequate lighting exist				
4.	Adequate electrical/power supply for the equipment				
5.	An adequate water supply exists (free flowing water from the faucet in the work area and in the hand washing area)				
6.	Alarm and sprinkler system is in good working condition				
7.	Emergency shower and eye wash is in good working condition				
8.	Back-up generator is in good working condition				
9.	Documented program for proper maintenance and monitoring of physical plant and facilities				
	Biosafety Standards				
1.	Documented procedure/ process on laboratory biosafety and biosecurity and for the proper disposal of waste and hazardous/infectious substances.				

B. GOVERNMENT STANDARDS COMPLIANCE

	Indicators	Yes	No	In Progress	Remarks
	<i>The laboratory must comply with the following certificates and permits, which should be valid, current, and posted conspicuously in the reception area:</i>				
1.	Fire Safety Inspection Certificate				
2.	DTI/SEC registration/Enabling Act Resolution				
3.	Mayor's Permit				
4.	Annual Building Inspection Certificate				

C. OTHER SUPPLIES AND FIXTURES

	Indicators	Yes	No	In Progress	Remarks
1.	Cabinets are orderly, safe and are in good condition				
2.	Tables and chairs are sufficient for the number of personnel				
3.	Supply of filter paper cards exists and storage meets NSRC requirements				
4.	Supply of lancets exists and storage is safe				
5.	Residual specimen cards are stored in an appropriate space and in an orderly fashion				
6.	Supply of gloves for employee use exist and are appropriately used. Ensure appropriate material and size.				