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OFFICE OF THE SECRETARY

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October 22, 2004

DEPARTMENT CIRCULAR

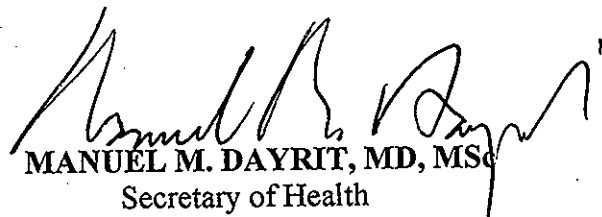
No. 333 s. 2004

TO: THE UNDERSECRETARIES, ASST. SECRETARIES,
CHD/BUREAU/ SERVICE PROJECT/PROGRAM DIRECTORS,
MEDICAL CENTER CHIEFS OF SPECIAL/SPECIALTY
HOSPITALS, EXECUTIVE DIRECTOR OF DANGEROUS DRUGS
BOARD, PRESIDENT OF THE PHIC AND OTHERS CONCERNED

SUBJECT: Rules and Regulations Implementing Republic Act No. 9288
Otherwise Known as the "Newborn Screening Act of 2004"

Attached for information and guidance, is a copy of the Rules and Regulations Implementing Republic Act No. 9288 otherwise known as the "Newborn Screening Act of 2004."

Dissemination of the information to all concerned is desired.


MANUEL M. DAYRIT, MD, MSc
Secretary of Health

Smoking is hazardous to your health



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**RULES AND REGULATIONS
IMPLEMENTING REPUBLIC ACT NO. 9288
OTHERWISE KNOWN AS
THE "NEWBORN SCREENING ACT OF 2004"**

The following Rules and Regulations are hereby promulgated to implement the Republic Act No. 9288 otherwise known as "Newborn Screening Act of 2004", an act promulgating a comprehensive policy and a national system for ensuring newborn screening.

RULE 1 POLICY AND APPLICATION

Sec. 1. *Purpose:* These Implementing Rules and Regulations shall provide the concerned national government agencies, local government units and other public institutions, non-government organizations, people's organizations and private institutions with guidelines for the implementation of a comprehensive national policy institutionalizing the newborn screening system to ensure that every baby born in the Philippines is offered the opportunity to undergo newborn screening.

Sec. 2. *Declaration of Policy* – It is the policy of the State to protect and promote the right to health of the people, including the rights of children to survival and full and healthy development as normal individuals. In pursuit of such policy, the State shall institutionalize a National Newborn Screening System that is comprehensive, integrative and sustainable, and will facilitate at the national and local levels, collaboration among government and non-government agencies, the private sector, families and communities, professional health organizations, academic institutions, and non-governmental organizations. The National Comprehensive Newborn Screening System shall ensure that every baby born in the Philippines is offered the opportunity to undergo newborn screening and thus be spared from heritable conditions that can lead to mental retardation and death if undetected and untreated.

Sec. 3. *Objectives* – National Comprehensive Newborn Screening System shall aim to:

- a) Ensure that every newborn has access to newborn screening for certain heritable conditions that can result in mental retardation, serious health complications or death if left undetected and untreated;
- b) Establish and integrate a sustainable newborn screening system within the public health delivery system;
- c) Ensure that all health practitioners are aware of the advantages of newborn screening and of their respective responsibilities in offering newborns the opportunity to undergo newborn screening; and
- d) Ensure that parents recognize their responsibility in promoting their child's right to health and full development, within the context of responsible parenthood, by protecting their child from preventable causes of disability and death through newborn screening.

Sec. 4. *Definition of Terms* – For the purposes of this Act:

- a) **Accreditation** - a formal authorization issued by the DOH to an individual, partnership, corporation or association and to the Newborn Screening Center. It must comply with the mandatory requirements as enumerated in the attached annexes and with the input, process and outcome standards as prescribed in the Manual of Operations for Newborn Screening Center.
- b) **DILG** – refers to the Department of the Interior and Local Government
- c) **DOH** - refers to the Department of Health, the lead agency in implementing this Act
- d) **Follow-up** - refers to the monitoring of a newborn with a heritable condition for the purpose of ensuring that the newborn patient receives the appropriate medicine or dietary prescriptions.
- e) **Health institutions** - refer to hospitals, health infirmaries, health centers, lying-in centers or puericulture centers with obstetrical and pediatric services, whether public or private.
- f) **Healthcare practitioner** - refers to physicians, nurses, midwives, nursing aides and traditional birth attendants.

- g) **Health professional societies** - refer to the national organizations of recognized health societies in the country.
- h) **Heritable condition** - any condition that can result in mental retardation, physical deformity or death if left undetected and untreated and which is usually inherited from the genes of either or both biological parents of the newborn.
- i) **IRR**- refers to the Implementing Rules and Regulations.
- j) **LGU** - refers to the Local Government Unit.
- k) **National Comprehensive Newborn Screening System-Treatment Network** – refers to the tertiary hospitals equipped to diagnose and manage the confirmed cases.
- l) **NIHP** - refers to the National Institutes of Health, Philippines.
- m) **Newborn** - a child from the time of complete delivery to thirty (30) days old.
- n) **Newborn screening (NBS)** - the process of collecting a few drops of blood from the newborn onto an appropriate collection card and performing biochemical testing for determining if the newborn has a heritable condition.
- o) **Newborn Screening Center (NSC)**- a facility equipped with a newborn screening laboratory that complies with the standards established by the NIHP, and provides all required laboratory tests and recall/follow-up programs for newborns with heritable conditions.
- p) **Newborn Screening Reference Center (NSRC)**- central facility at the NIHP that defines testing and follow-up protocols, maintains an external laboratory proficiency testing program, oversees the national testing database and case registries, assists in training activities in all aspects of the NBS program, oversees content of educational materials, recommends establishment of NSCs and acts as the Secretariat of the Advisory Committee on Newborn Screening.

- q) **Newborn Screening Specimen Collection Kit** – materials needed in collecting NBS samples namely, filter collection card, lancet, information materials, , etc, which can be procured at the NSC.
- r) **Parent Education** - the various means of providing parents or legal guardians information about NBS.
- s) **Participating Health Institutions** – health institutions offering newborn screening services such as, but not limited to, motivation of parents, collection of blood sample and recall.
- t) **PHIC** - refers to the Philippine Health Insurance Corporation.
- u) **Recall** –a procedure for locating a newborn with a positive screening results from a possible heritable condition for purposes of providing that newborn with appropriate laboratory testing to confirm the diagnosis and, as appropriate, to provide treatment.
- v) **Treatment** –provision of prompt, appropriate and adequate medicine, medical and surgical management or dietary prescription to a newborn for purposes of treating or mitigating the adverse health consequences of a heritable condition.
- w) **UP** - refers to the University of the Philippines.

RULE II NATIONAL COMPREHENSIVE NEWBORN SCREENING SYSTEM.

Sec. 5. *National Comprehensive Newborn Screening System (NCNBSS)* shall refer to a NBS system that includes, but is not limited to:

- a) Education of relevant stakeholders;
- b) Collection, transport, biochemical screening, and reporting on result of blood samples taken from newborns;
- c) Tracking and confirmatory testing to ensure the accuracy of screening results;
- d) Clinical evaluation and biochemical/medical confirmation of follow-up test results;

- e) Administration of drugs and/or medical surgical management and/or dietary supplementation to counter adverse effects of the heritable conditions; and
- f) Monitoring and evaluation of the NCNBSS.

Sec. 6. *Obligation to Inform.* Any health practitioner who delivers, or assists in the delivery, of a newborn in the Philippines shall, prior to delivery, inform parents or legal guardian of the newborn of the availability, nature and benefits of NBS. Health practitioners shall follow the DOH prescribed guidelines on notification and education relative to the obligation to inform. The DOH, other Government agencies, non-government agencies, professional societies and LGU shall make available appropriate information materials and shall have a system of its distribution. The health practitioner shall maintain documentation in the patient's records that NBS information has been provided.

Sec 7. *Performance of NBS.* --NBS shall be performed after twenty-four (24) hours of life but not later than three (3) days from complete delivery of the newborn. A newborn placed in intensive care in order to ensure survival may be exempted from the three (3)-day requirement but should be tested by seven (7) days of age.

- a) Compliance to NBS shall be the joint responsibility of the parent(s)/legal guardians and health practitioner or other person delivering the newborn to ensure that NBS is performed;
- b) Health practitioners shall fully inform their patients' parents, or legal guardians about the availability, nature, and benefits of NBS;
- c) Collection of samples may be performed by any trained health worker such as physicians, medical technologists, nurses and midwives;
- d) NBS specimens shall be properly transported to the accredited NSCs by courier or any other fast and timely mode of transport within twenty four (24) hours following collection of the sample;
- e) NBS laboratory testing shall be performed by DOH-accredited NSCs.

Any laboratory results indicating an increased risk of a heritable disorder (i.e. positive testing result) shall be immediately released, within twenty-

four (24) hours, so that confirmatory testing can be performed as provided in Section 8.

Negative screens shall be released seven (7) working days after receipt at the NSC.

Sec. 8. *Recall.* A newborn with a positive result shall be located and recalled for confirmatory testing as soon as possible.

- a) A newborn identified at high risk (positive screening result) for a heritable disorder shall be recalled immediately to confirm the diagnosis. The Municipal Health Office, City Health Office, Provincial Health Office and District Health Office shall be involved in the recall process;
- b) The NSC shall notify the participating health institution about the immediate recall of the newborn with a positive screening result. Every collecting health facility shall designate a person or office responsible in the recall of the newborn;
- c) The NSC shall likewise inform the designated person of the CHD or its equivalent to assist in the immediate recall of newborn with positive screen;
- d) The attending health practitioner shall assist the participating health institution in locating and recalling the patient;
- e) Once located, the newborn with confirmed diagnosis shall be referred for treatment and management to a duly licensed physician or a medical specialist such as but not limited to, neonatologist, pediatric endocrinologist and geneticist. Prompt management of newborns with positive screen is essential to prevent the debilitating consequences or death of the newborn;
- f) Once contacted, the parents with assistance of the respective LGU shall have the primary responsibility to ensure that their newborn receive appropriate confirmatory testing as soon as possible.

Sec. 9. *Referral and Management of Positive Cases.*

- a) The total management of patient with confirmed diagnosis shall be referred to the NCNBSS Treatment Network;

- b) All NCNBSS Treatment Network shall follow the DOH- approved clinical protocol in the management of patients diagnosed in any of the disorders included in the newborn screening panel.

Sec. 10. *Monitoring of patients.* Monitoring and follow up of patients confirmed to have the disorders shall be done regularly by the attending physician, appropriate subspecialist or Rural Health Unit (RHU).

Report forms about the status of the patients shall be accomplished by the attending physicians to be submitted to the NSCs.

Sec. 11. *Refusal to be Tested.* A parent or legal guardian may refuse testing on the grounds of religious beliefs, but shall acknowledge in writing their understanding that refusal for testing places their newborn at risk for mental retardation or death of undiagnosed heritable conditions. A copy of this refusal documentation shall be made part of the newborn's medical record and refusal shall be indicated in the national NBS database.

Sec. 12. *Continuing Education, Re-education and Training of Health Personnel.* To ensure awareness of all health personnel, the DOH, LGUs, and the academe with the assistance of the NIHP and other government agencies, professional societies and non-government organization shall:

- a) Conduct continuing information, education, re-education and training programs for health personnel on the rationale, benefits, procedures of NBS;
- b) Disseminate information materials on NBS at least annually to all health personnel involved in maternal and pediatric care;
- c) Integrate information in existing education programs for medical and paramedical professionals.

RULE III IMPLEMENTATION

Sec. 13. *Lead Agency.* The DOH shall be the lead agency for implementing the NCNBSS. DOH shall have the following responsibilities:

- a) Fully utilize the efforts and resources of various offices within the DOH, NIHP, PHIC, and health facilities, concerned health personnel and workers to implement the NCNBSS;

- b) Establish the Advisory Committee on Newborn Screening (ACNBS);
- c) Coordinate with the Department of the Interior and Local Government for implementation of the NCNBSS;
- d) Coordinate with the NSRC for the accreditation of NSC and preparation of defined testing protocols and quality assurance programs;
- e) Coordinate with all health professional societies in an advocacy campaign on behalf of the comprehensive NBS system;
- f) Integrate NBS in the current health care delivery system. NBS shall be an integral part of all public health programs. It should be a routine procedure for newborns in public and private health, hospital and birthing facilities;
- g) Ensure that a network for the prompt recall of positive cases is established in collaboration with LGUs, government agencies and other Non Government Organizations;
- h) Ensure that a network of facilities for referral and management of all positive cases is established;
- i) Formulate protocols in the referral and management of the positive cases in collaboration with the Philippine Society for Pediatric Metabolism and Endocrinology and the Institutes Human Genetics – NIHP;
- j) Develop referral centers and identify referral teams in strategic areas for referral and management of patients with any of the disorders;
- k) Ensure inter-agency collaboration through inclusion of NBS in the agenda of existing committees on children's health and welfare. In such venues, the following agencies shall be represented: DOH, NIHP, DILG and other relevant health professional organizations;
- l) Ensure quality and sustainability of NBS system through the establishment of NSRC as well as its attendant requisites.

Sec 14. Major Stakeholders. To ensure implementation of NCNBSS, the agencies/organization identified below shall have the following responsibilities:

A. Health Facilities, i.e. Hospitals, birthing facilities, rural health units and health centers

- a) Integrate NBS in its delivery of health services;
- b) Serve as collecting health facility for NBS;
- c) Coordinate with a duly accredited NSC;
- d) Ensure that adequate and sustained NBS services such as information; education, communication, screening, recall and management of identified cases are being provided in the hospital;
- e) Establish a NBS Team that will be responsible for the following: collection of samples, sending of samples to accredited NSC, prompt recall of positive patients, referral and management of patients;
- f) Establish an appropriate financial system that will ensure effective and efficient collection of fees and payment of NBS services to the NSC;
- g) Conduct orientation and/or training of hospital staff on NBS;
- h) Monitor and evaluate the implementation of NBS within the institution;
- i) Define creative financial packages to make NBS accessible particularly among the economically deprived populace.

B. Department of the Interior and Local Government shall:

- a) Encourage LGUs to implement RA 9288, "The Newborn Screening Act of 2004" and extend total cooperation in the implementation of the said law;
- b) Assist the DOH in the monitoring and evaluation of the program implementation.

C. Local Government Units shall:

- a) Develop capabilities of health workers;
- b) Issue local ordinances and resolutions that integrate NBS in the delivery of health delivery system;
- c) Ensure that adequate and sustained NBS services such as information, education, communication, screening, recall and follow-up are being provided in all LGU Health facilities (Rural Health Unit/ City Health Unit, Lying-ins, City/Municipal/ District/ Provincial Hospitals);
- d) Establish a functional case management referral system with strategically accessible NCNSS treatment network;
- e) Establish coordination and networking among concerned agencies in NBS implementation;
- f) Monitor and evaluate the newborn screening implementation in their localities;
- h) Explore/encourage creative financial packages to make NBS accessible particularly among the economically deprived populace;
- i) Perform other roles and responsibilities as deemed necessary for the implementation of this Act.

D. Academe, Health Professional Societies, National Organizations of Health Professionals shall:

- a) Ensure that all its members are aware of the significance of NBS to their clients, their families and the society at large;
- b). Define mechanism that will ensure and monitor that its members are doing their obligations to inform parents about the significance of NBS;
- c). Recommend the inclusion of NBS as part of the curricula of all allied health professions;

E. Council for the Welfare of Children shall:

- a) Integrate NBS in the establishment of the system for early identification, prevention, referral and intervention of developmental disorders and disabilities in early childhood;
- b) Promote NBS as an integral part of the Early Childhood and Care Development (ECCD) programs implemented at the national and local levels;
- c) Provide avenues in developing innovative advocacy and communication approaches in partnership with civil societies, NGOs and other groups;
- d) Include NBS-related indicators in the Subaybay Bata and Macro-Monitoring system for children.

RULE IV ADVISORY COMMITTEE ON NEWBORN SCREENING

Sec. 15. *Advisory Committee on Newborn Screening (ACNBS).* To ensure sustained inter-agency collaboration, the ACNBS shall be created and made an integral part of the Office of the Secretary of the DOH.

Sec. 16. *Functions.* The ACNBS shall have the following functions:

- a) Review annually and recommend conditions to be included in the NBS panel of disorders;
- b) Review and recommend the standard NBS fee to be charged by NSCs;
- c) Review the report of the NSRC on the quality assurance of the NSCs; and
- d) Recommend corrective measures as deemed necessary.

Sec. 17. *Composition of the Committee.* The Committee shall be composed of eight (8) members:

- a) Secretary of Health, who shall act as Chairperson;
- b) Executive Director of the NIHP, who shall act as Vice Chairperson;
- c) Undersecretary of the DILG;
- d) Executive Director of the Council for the Welfare of Children;
- e) Director of the NSRC; and
- f) Three (3) representatives appointed by the Secretary of Health who shall either be a pediatrician, obstetrician, endocrinologist, family physician, nurse or midwife, from either the public or private sector. The three (3) representatives shall be appointed for a term of three (3) years, subject to their being reappointed for additional three (3) year periods for each extension.

Sec. 18. *Meetings.* The ACNBS shall meet at least twice a year. The NIHP shall serve as the Secretariat of the Committee.

RULE V NEWBORN SCREENING FEES

Sec. 19. *Newborn Screening Fees.*

- a) Expenses for the NBS tests shall be the responsibility of the parents/guardian of the newborn;
- b) The government and private health facilities are highly encouraged to develop a scheme providing partial or full subsidy depending on the financial capability of the parents;
- c) A standard NBS fee covering all program costs shall be implemented by all NSCs, as approved by the ACNBS. A payment schedule shall also be imposed on all participating health institutions so that the NSC may stay financially solvent;
- d) A health facility may collect a reasonable fee for the collection of samples, which shall not be greater than the maximum allowable service fee prescribed by DOH.
- e) NSRC shall collect the percentage of the NBS fees earmarked for the DOH - Centers for Health Development (CHD) or its future

equivalent from all hospitals, birthing facilities and other collecting units;

- f) NSRC shall transfer earmarked funds to all DOH CHDs or its future equivalent..

Sec. 20. *PHIC Benefit Package and Other Health Insurance-Related Concerns.*

- a) The PHIC shall include cost of NBS in its benefit package of its members;
- b) PHIC shall only reimburse NBS tests done in DOH accredited NSCs;
- c) A newborn shall be considered a dependent of a PHIC member;
- d) Newborn Screening for disorders included in the NBS panel approved by ACNBS shall be considered nationally accepted screening tests for inborn errors of metabolism and shall be considered as "medically necessary";
- e) For other health facilities, i.e. lying in and birthing facilities, PHIC shall develop a reimbursement scheme to cover the newborns similar to the benefits of newborns born in the hospital facilities;
- f) Private insurance companies, Health Management Organizations and community-based health care organizations shall include payment for NBS as a standard benefit to their members.

Sec 21. *NBS Specimen Collection Kits*

- a) All hospitals, birthing facilities, Rural Health Units, Health Centers and other collecting units throughout the country shall have NBS Specimen Collection Kits at all times;
- b) The cost of the NBS Specimen Collection Kits shall be based on the amount prescribed by the ACNBS;
- c) Members of the PHIC may apply for reimbursement of the cost of NBS Specimen Collection kits;

- d) For indigent members, PHIC shall devise a scheme that shall not entail a cash advance for NBS.

SEC 22. *Usage of NBS Fees.* Guidelines on the usage of funds, as approved by the ACNBS, shall be formulated by the NIHP and DOH. The NBS fee shall be applied to, among others, testing costs, education, sample transport, follow-up and reasonable overhead expenses. To ensure sustainability of the NCNBSS, the NBS fee shall be divided and set aside for the following purpose:

- a) At least four percent (4%) to the DOH - CHDs or its future equivalent for:
- i. Follow-up service of patients with positive screening result by personnel hired for the NBS unit based at CHD;
 - ii. Education and other activities directly related to the provision of NBS services;
 - iii. Incentives for RHU collecting health units at least 2 % of the money allocated to the CHD;
 - iv. Staff development of the personnel of the NBS unit based at the CHD, i.e. attendance of training seminars and official meetings of the DOH and the NIHP,
 - v. Capital outlay, i.e. vehicle
 - vi. Maintenance and operating expenses of the program
 - vii. Cost of repeat samples due to insufficient and unsatisfactory samples of patients in their catchment area
- b) At least four percent (4%) to the NSC for human resource development and equipment maintenance and upgrading;
- c) At least four percent (4%) to the NIHP-NSRC for overall supervision, training and continuing education, maintenance of national database, quality assurance program and monitoring of the national program; and
- d) The balance for the operational and other expenses of the NSC.

RULE VI NEWBORN SCREENING CENTERS

Sec. 24. *Establishment of Newborn Screening Centers (NSC).*

- a) No NSC shall be allowed to operate unless it has been duly accredited by the DOH based on the standards and procedural guidelines approved by the Committee as enumerated in the attached annexes, which is an integral part of this IRR and the Manual of Operations for NSC formulated by the NSRC;
- b) The establishment and accreditation of either free-standing or hospital-based NSC shall be phased. It shall take into consideration: strategic and geographical access to the public, data on the number of live births in each of the following areas in relation to the minimum required number of tests run (at least 50,000 samples per annum), the network component including the availability of courier services and the other NCNBSS policies.

Initially, there shall be four (4) NSCs to serve the whole country. However additional NSCs shall be established upon the recommendation of the NSRC;

- d) NSCs shall make available their records to the team, including their financial books to determine compliance with fee structures and other accreditation rules and regulations.

Sec. 24. *Licensing and Accreditation.*

- a) The DOH through the Bureau of Health Facilities and Services (BHFS) shall include, among others, the provision of NBS services in the licensing requirements for hospitals and birthing facilities;
- b) PHIC shall include, among others, proof of NBS services in the accreditation of health facilities for quality pediatric services;
- c) The NSC shall issue proof of NBS services.

RULE VII ESTABLISHMENT OF NEWBORN SCREENING REFERENCE CENTER

Sec. 26. *Establishment of a Newborn Screening Reference Center (NSRC).* The NIHP shall establish a NSRC. It has the following functions:

- a) Be responsible for the national testing database and case registries, training, technical assistance and continuing education for laboratory staff in all NSCs;
- b) Define the testing and follow-up protocols for NSCs;
- c) Maintain an external laboratory proficiency-testing program;
- d) Oversee the national testing database and case registries;
- e) Report to the DOH the NSCs found violating these rules and regulations and those performing and providing NBS procedures and services without any DOH accreditation;
- f) Participate in consultation and evaluation activities initiated by BHFS in relation to the NSRC and the NSCs performance and in improving implementation of these rules and regulations.

Sec. 27. *Quality Assurance.* All NSC's shall strictly follow the prescribed guidelines of good laboratory practices. The NSRC shall be responsible for drafting and ensuring good laboratory practice standards for NSCs, including establishing an external laboratory proficiency testing and certification program. It shall also act as the principal repository of technical information relating to NBS standards and practices, and shall provide technical assistance to NSCs needing such assistance.

Sec. 28. *Database.*

- a) All NSCs shall coordinate with the NSRC for consolidation of patient databases;
- b) The NSRC shall maintain a national database of patients tested and a registry for each condition;
- c) The NSRC shall submit reports semi-annually or more frequently as the need arises to the ACNBS and to the DOH on the status of and relevant health information derived from the database.


NSRC shall prepare a plan for long-term outcome evaluation of NBS utilizing the cases registries. The plan shall be developed within one (1) year of passage of this Act in consultation with the ACNBS. Implementation of this plan shall become a responsibility of the ACNBS.

RULE VIII FINAL PROVISIONS

Sec. 29. Repealing Clause – All general and special laws, decrees, executive orders, proclamations and administrative regulations, or any parts thereof, which are inconsistent with this Act are hereby repealed or modified accordingly.

Sec. 30. Separability – If, for any reason, any part of provisions of this Act shall be declared or held to be unconstitutional or invalid, other provision or provisions hereof which are not affected thereby shall continue to be in full force and effect.

Sec. 30. Effectivity – This Act shall take effect fifteen (15) days after its publication in at least two (2) newspapers of general circulation.


MANUEL M. DAYRIT, MD, MSc.
Secretary of Health

MANDATORY ACCREDITATION REQUIREMENTS FOR NSCS**1. SERVICE CAPABILITY****1.1 Testing Capability:**

- 1.1.1** Analyzing a minimum of one hundred and fifty (150) samples a day utilizing testing methods approved by the NSRC
- 1.1.2** Testing for the following disorders included in the NBS package currently approved by the ACNBS for NBS:
 - 1.1.2.1** Congenital Adrenal Hyperplasia (CAH)
 - 1.1.2.2** Congenital Hypothyroidism (CH)
 - 1.1.2.3** Phenylketonuria (PKU)
 - 1.1.2.4** Galactosemia (GAL)
 - 1.1.2.5** Glucose 6 Phosphate Dehydrogenase Deficiency (G6PD)
- 1.1.3** Interpreting and reporting test results for each disorder based on pre-determined analytical ranges and expected norms.

1.2 Administrative and Network Capability:

- 1.2.1** Providing the necessary NBS Specimen Collection Kits (filter collection card, lancets, information materials, etc) to all health facilities within its coverage.
- 1.2.2** Releasing results of all analytical testing for all samples received from health facilities within its coverage.
- 1.2.3** Informing NBS coordinators of health facilities of patients whose results are positive or unsatisfactory at the time of initial screening.
- 1.2.4** Monitoring and referring patients with abnormal results to NCNSS treatment network.
- 1.2.5** Coordinating with government and non-government agencies for the establishment of a network for NBS recall and follow-up.
- 1.2.6** Establishing and maintaining databases of patients screened, analytical results, and follow-up outcome.
- 1.2.7** Providing required information from databases to NSRC via computerized linkages
- 1.2.8** Transporting samples from the health facilities to the NSC

- 1.2.9 Receiving specimens on a daily basis five (5) working days per week from courier or other appropriate delivery services
- 1.2.10 Storing specimens in a manner deemed appropriate
- 1.2.11 Maintaining detailed documentation logs of testing and follow-up.

2. PERSONNEL

- 2.1 A licensed physician with at least one (1) year training/ orientation and experience in running a NBS program or three (3) years of equivalent experience in a closely allied situation as approved by the NSRC.
- 2.2 A licensed biochemist, chemist, medical technologist or microbiologist with at least one (1) year of satisfactory training/ orientation in NBS Laboratory Management or three (3) years of experience in related field.
- 2.3 Three appropriately licensed scientists (biochemist, chemist, medical technologist or microbiologist) with at least three (3) months of laboratory testing experience in performing the tests specified or one (1) year of equivalent testing experience in a clinical laboratory.
- 2.4 A licensed nurse with at least three (3) months of experience working/training in NBS or six (6) months of equivalent experience in a public health case management program.

3. EQUIPMENT/ INSTRUMENT/ REAGENTS

- 3.1 Database system compatible with that of the NSRC
- 3.2 Equipment appropriate for performing analytical testing on dried blood spots (3 mm diameter - ~1.5 μ L serum) for Congenital Hypothyroidism, Congenital Adrenal Hyperplasia, Phenylketonuria, Galactosemia and Glucose-6-Phosphate Dehydrogenase deficiency
- 3.3 Fume hood necessary for any of the analytical procedures specified
- 3.4 Automated puncher capable of cleanly punching 3 mm paper punches
- 3.5 Manual paper punch capable of cleanly punching 3 mm paper punches
- 3.6 Multiple pipettor capable of delivering appropriate reagent volumes for any of the procedures specified (i.e. generally considered to be volumes of 10 μ l, 50 μ l or 100 μ l)
- 3.7 Eppendorf pipettes, if deemed appropriate, calibrated to deliver volumes of 100 μ l and 200 μ l

- 3.8 Filter paper collection cards (S&S 903) compatible with those designed for use by the NSRC
- 3.9 Lancets with tip approximately 2.0 mm long sufficient for heel-prick
- 3.10 Disposal system for hazardous and non-hazardous materials
- 3.11 Drying rack for horizontal drying of filter paper collection cards
- 3.12 Storage area of used filter paper cards (a small room with temperature and humidity control is preferred)
- 3.13 Freezer with temperatures maintained between -20 to -10 °C
- 3.14 Refrigerator capable of maintaining constant temperatures between 4-8 °C.

4. FACILITY

- 4.1 Minimum of one hundred (100) square meters working floor area
- 4.2 Area for blood collection and storage
- 4.3 Five (5) work-benches to run the five (5) tests. Each work bench approximately three (3) ft. long and five (5) ft. wide.
- 4.4 Sink for waste disposal
- 4.5 Source of de-ionized water
- 4.6 Waste disposal facilities for any hazardous materials generated

GUIDELINES IN THE APPLICATION FOR ACCREDITATION

A Certificate of Accreditation shall be granted in accordance with the prescribed accreditation requirements and on the basis of specific conditions and limitations. The accreditation as herein granted as well as any right under the accreditation cannot be assigned or otherwise transferred directly or indirectly to any party. A separate accreditation shall be required for all NSC or branches maintained in separate premises. Violation of this IRR, its Manual of Operations for NSC and other related issuances shall be a ground for suspension or revocation of the accreditation.

1. PROCEDURES FOR APPLICATION OF ACCREDITATION:

- 1.1 Applicant requests for relevant information and prescribed forms from the BHFS on the proposed NSC, in person, or through mail, e-mail, fax transmittal or the internet.
- 1.2 Applicant accomplishes required documents and submits them in person or through mail to the BHFS

Documentary Requirements:

Initial Accreditation:

- a. BHFS-NSC Form No. 1-01: Application for DOH Accreditation as a NSC
- b. List of personnel involved in NBS, indicating names, positions, job description, PRC license number and relevant training
- c. List of equipment/instrument/ reagents for NBS if available
Letter of Intent signifying willingness to:
 - comply with the prescribed Technical and Administrative Manual of Operations for NBS, and
 - participate in Quality Assurance Program

Renewal of Accreditation:

BHFS-NSC Form No. 2-01: Application for Renewal of DOH Accreditation as a NSC

- a. List of Personnel involved with NBS, indicating names, positions, job description, PRC license number and relevant training
- b. List of equipment/instrument/ reagents for NBS

- c. List of NBS procedures performed, services offered and statistical accomplishment report for the past three (3) years
- d. Copy of the NSCs Technical and Administrative Manual of Procedures for NBS.
- e. Documentation of Quality Assurance Program implementation

- 1.3 BHFS together with NSRC evaluates application based on the selection criteria that includes the pre-identified regional areas for NSCs to serve and compliance with documentary requirements
- 1.4 BHFS informs the applicant of the result of evaluation. If favorable, applicant for initial accreditation is informed to set-up the facility for an ocular inspection and payment of the prescribed accreditation fees to the Cashier of the DOH, in cash or through postal money order.
- 1.5 BHFS and NSRC conduct ocular inspection in accordance with NSC technical requirements.
- 1.6 The BHFS and NSRC recommend approval or disapproval upon inspection.
- 1.7 The Director of the BHFS signs approval or disapproval of application for accreditation.

If approved, the BHFS registers the health facility as a NSC and issues the corresponding certificate of accreditation to the applicant.

If disapproved, the BHFS sends the findings, recommendations to the applicant who makes the necessary alterations and/or corrections within fifteen (15) days from the time of inspection. The applicant then requests the BHFS for another inspection. Failure to make necessary corrections of deficiencies within fifteen (15) days after due notice, results to forfeiture of application and accreditation fee.

B. VALIDITY AND EXPIRATION:

- 1. The Certificate of Accreditation shall have a validity period of three (3) years subject to periodic monitoring.
- 2. Application for renewal of accreditation not filed within thirty (30) days after expiration shall be treated as a new application.