Southeast Regional Newborn Screening Backup Strategy, Version 1.0 (July 2013)
Emergency Support for a Mission Essential Function

SouthEast Regional NBS & Genetics Collaborative
2165 North Decatur Road
Decatur, GA 30033-5307

ABSTRACT
A contingency plan available to the States of Florida, Georgia, Louisiana, North Carolina, South Carolina and Tennessee focused on maintenance of newborn screening services.
The Southeast Regional NBS Backup Strategy is the combined effort of the Southeast Regional Genetics Collaborative (SERC) and its Laboratory and Emergency Preparedness Workgroups.

**Disclaimers:**
This document, which has been created by the Southeast Regional Genetics Collaborative is intended to serve as a concept of operations document for each state and regional efforts. The document is a set of guidelines for reference and is **not a legally binding document**. Any guidelines are strictly meant as suggestions for consideration.

This publication was developed under funding from a grant from the Maternal and Child Health Bureau (MCHB) (Title V, Social Security Act) Grant #H46MC24090 Health Resources and Services Administration (HRSA), Department of Health and Human Services (DHHS). The opinions expressed here are not necessarily those of the MCHB, HRSA or DHHS.
Preface

Background
Newborn screening (NBS) is the process of testing newborns for treatable genetic disorders that lead to endocrinologic, metabolic and hematologic diseases. NBS has evolved over the past few decades to be a critical capacity of state public health laboratories in all state and territories of the United States as mandated by state and federal law.

NBS is divided into two basic components: the analysis of blood spot samples and the follow-up with the newborn’s family and care providers. NBS is a screening tool as it does not provide definitive diagnosis of a disorder. Therefore the ultimate goal of NBS is to notify family and caregivers that the child is either not at risk or has screened positive to an inheritable disorder, or may need further consultation and testing to determine if the child is impacted by an inheritable disorder.

This system supports an array of healthcare infrastructure including birthing centers (hospitals, etc.) and ambulatory care centers (OB-GYN, pediatricians, and specialized care providers – found in genetics clinics, etc.). NBS is also about the development and supply of sample collection devices commonly the blood spot card that also is a device for collecting demographic data on the newborn and his/her parents. The blood spot card is utilized for a range of purposes including quality control within the laboratory, as well as demographic data collection within the public health system.

In 2008, Congress delineated this system’s critical capacity in the Newborn Screening Saves Lives Act and mandated the development of a national contingency plan by the Department of Health and Human Services (DHHS). DHHS developed the National NBS Contingency Plan (CONPLAN) in 2010 further identifying necessary functionality including backup capacity development between the various state NBS laboratories or their contractor laboratories.

In 2011, the Centers for Disease Control (CDC) contracted with the Association of Public Health Laboratories (APHL) to develop the APHL document on public health laboratories. This document (see reference list) was published in February 2011 and was shortly followed (March 2011) by CDC’s Public Health Emergency Preparedness Capabilities. Both documents included reference to routine public health testing, such as NBS, as focuses of public health authority COOP development.

In November, 2012, members of each state and territory were involved in an organizing meeting, supported by the National Newborn Screening and Global Resource Center (NNSGRC), whose goal was to develop a specific NBS lab backup plan for each state and territory. This group is designated as the SERC Lab Backup Workgroup. The current document is a working strategic plan that was initiated at this meeting.

How To Use This Plan
The SERC NBS Backup Strategy is intended to be a non-binding presentation of the potential actions that the region’s NBS laboratories can take when faced with loss of capacity. The plan assumes that each state makes independent decisions about their NBS programs, laboratories and
backup for these services. The basis of this document is a Memorandum of Understanding developed by the states of Florida and Texas (see Appendix A).

Each party to action, as described within the Concept of Operations, is designated as either the requesting lab or the supporting lab. Each party is expected to undertake the preparedness and mitigation actions listed within the Roles and Responsibilities section. These actions will lead to improved readiness, particularly on the part of a potential requesting lab to initiate backup in an emergency.

**Purpose**
This document exists to describe how several of the 10 states and territories of the Southeast Regional Genetics Collaborative (SERC) will pursue emergency backup of NBS services of one or more of the member state(s) by the State of Florida’s NBS program.

**Desired Response End State**
The response described in the concept of operations section of this plan is complete when the requesting program(s) is able to resume delivery of its NBS services and the samples submitted to the support laboratory have been returned to the requesting state, or disposed of by the supporting laboratory per the policy of the requesting state and documentation of that disposal has been supplied to the requesting program(s).

**Objectives**

**Strategic Objectives**
This plan seeks to accomplish the following objectives:

- Present an approach usable by any state or territory within the SERC’s area of interest for emergency backup of its NBS laboratory.
- Identify activities that a requestor and the supporting NBS laboratory will or can to accomplish between now and the first emergency backup activation.

**Mapping to National-Level Objectives**
The concept of operations section describes response objectives that match the following national public health preparedness objectives:
This plan, when acted upon, leads the host public health authority to completion of priority #3 (P3): “Written plans should include processes and protocols for continuity of operations.” “Continuity of Operations [planning] should … also [include] routine testing such as the assurance of newborn screening.”

This document is written in a format that leads to use as an annex to the health authority’s Continuity of Operations Plan.

The concept of operations section also matches with the following National NBS Contingency Plan (CONPLAN) objectives:

**Table 2 - National NBS CONPLAN Objectives Map**

<table>
<thead>
<tr>
<th>NBS CONPLAN Objective</th>
<th>How Addressed by This Planning Initiative</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strategic Objective #2, All Operational Objectives</td>
<td>The plan describes a process by which samples, once collected are redirected to an alternate laboratory assuring minimal loss of samples by maintaining operational capacity to receive samples at the impacted laboratory even where activation of an alternate sample receiving area is required.</td>
</tr>
<tr>
<td>Assessment of need for activation is tied to pre-established Activation Thresholds that include consideration of turnaround time for samples in house. Additionally, alternate capacity to analyze is accomplished using an identified backup laboratory. Tracking of samples is accomplished using the backup LIMS and potentially duplication of tracking results is possible by accessioning of samples and entry of sample results in the impacted LIMS.</td>
<td></td>
</tr>
<tr>
<td>Strategic Objective #4, All Operational Objectives</td>
<td>This capacity is addressed by maintenance of the operational status of results review and reporting processes in the impacted laboratory and maintenance of communications between that facility and its follow-up coordination and care providers.</td>
</tr>
<tr>
<td>Strategic Objective #8, Operational Objective #1, Actions 4, 5 &amp; 10</td>
<td>This plan represents one element of an NBS program’s contingency plan. It includes activation process development (Activation Protocol). It includes development of relationships for backup and collection of best practice examples by plan administrators.</td>
</tr>
</tbody>
</table>
Participants

**Table 3 - Participants to Plan by Possible Role**

**Supporting Laboratories & Follow-up Services**

Florida (Primary Backup)

**Potential Requesting Laboratories & Follow-up Services**

Georgia
Louisiana
North Carolina
South Carolina
Tennessee

Terminology / Definitions

**Table 4 - Terminology Used in This Plan**

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Requestor</td>
<td>NBS program impacted and seeking support services from either the primary or secondary NBS program.</td>
</tr>
<tr>
<td>Supporter</td>
<td>NBS program that agrees to provide NBS services to one or more requesting NBS programs.</td>
</tr>
<tr>
<td>NBS Services</td>
<td>Either laboratory or follow-up services, or both</td>
</tr>
<tr>
<td>Laboratory Services</td>
<td>The qualitative analysis of blood spot samples for any of over 65 disorders. Analysis involves the use of a range of analytical methods and is qualitative in that the end reporting is that of a presumptive positive or negative as to the potential presence of the disorder within the subject, which is confirmed through referral to specialized medical care providers who complete the process of diagnosis, and if confirmed initiate follow-up care.</td>
</tr>
<tr>
<td>Follow-up Services</td>
<td>The program that reports NBS results to primary care physicians (PCP) and acts as liaison between the NBS lab and the patient/PCP.</td>
</tr>
</tbody>
</table>

Planning Assumptions

- Although both laboratory and follow-up service backup is possible under this plan, follow-up services are known to be less facility dependent and are less likely to be sought following an emergency which causes service disruption. Where services are detailed, they will generally focus on laboratory service backup but the absence of follow-up discussion is not intended to imply that these services cannot also be backed up by another state.
- Even though the Florida-Texas MOU is bi-directional and offers the possibility of directly accessing Texas support services by any program within the SERC area of
interest, this document assumes that the backup laboratory for the SERC region is Florida NBS Laboratory for the first version of this document.

- Activation of this plan requires interaction of the NBS laboratory management with programmatic and departmental management within the impacted state, and potentially between the public health authority (department) and the governor and/or state emergency management authority. Activation discussion in this plan focuses on the interaction between the impacted (requesting) laboratory and the supporting laboratory only.
- The process outlined in the Concept of Operations section is intended to present minimal disruption to the long-term business of the requesting laboratory in that sample receiving and results reporting capability is maintained throughout activation. The concept of operations presented assumes the development of contingency plans for maintenance/reconstitution of this capacity as part of operations.
- The concept of operations presented in this document is a recommendation and should not be considered prescriptive or binding.

**Concept of Operations**

The Concept of Operations (CONOPS) involves both the requesting laboratory and the supporting laboratory. Figure 1 shows major decision points along the process of receipt and processing of samples by the requesting laboratory through sample shipment, sample preparation, sample analysis, quality review and results reporting, all by the supporting laboratory. A central concept within this approach is maintaining the interaction between the requesting laboratory and its clientele.

**Activation**

Several concepts important to reaching a decision to activate this plan include:

- Activation Threshold (A.T.) - The number of days that a requesting laboratory can be unable to complete analysis before it becomes necessary to activate backup agreements. A laboratory’s A.T. depends on:
  - The average daily sample volume;
  - The specific lost capacity;
  - Time it will take for the repairs, calibration and required quality control testing to be completed for return of impacted systems to normal operations; and
  - Time required for the impacted laboratory systems to catch up on the backlog of samples while processing the continuing daily sample flow.

This data is taken into consideration in development of an A.T. that can be a number of deadlines, depending on the specific capability lost or day upon which the capability is lost, or a single deadline based upon some acceptable minimum or maximum. The A.T. may include a cost-benefit analysis.
**Figure 1 – CONOPS Overview**

**Requesting State Lab**

- **Activation**
  - Downtime will be > Act. Threshold? (NO → STOP)
  - YES → Initiate Activation Protocol

- **Receiving**
  - Is Sample Receiving operational? (NO → Relocate Sample Receiving, YES → Transfer samples)
  - Transfer samples

- **Analysis**
  - Are samples acceptable? (NO → ORDER RESAMPLING, YES → Process samples)
  - Process samples

- **Review**
  - Are results acceptable? (NO → ORDER RESAMPLING, YES → Algorithm issue?)
  - Algorithm issue? (NO → ORDER RESAMPLING, YES → Adequate sample for re-analysis?)
  - Adequate sample for re-analysis? (NO → ORDER RESAMPLING, YES → YES)

- **Reporting**
  - Report results to client? (NO → ORDER RESAMPLING, YES → Report results to Req. Lab)
  - Report results to Req. Lab

- **Remission**
  - Remit samples to Req. Lab (STOP)

**Supporting State Lab**

- **Activation**
  - Are you able to support? (NO → STOP)

**SERC**

- **Activation**
  - STOP
• Activation Protocol – A written plan detailing the steps taken to reach the decision to activate the backup plan. Ideally the protocol will:
  o Define the Activation Threshold,
  o Identify the supporting lab points of contact (including alternative POC), and
  o Define the process that lab management must pursue to activate backup agreement(s) and rapidly initiate backup services.

In the activation process, a laboratory identifies the need for potential backup, reviews its Activation Protocol, makes the determination if the Activation Threshold has been met, and if so, completes the Activation Protocol. This laboratory becomes the requesting or impacted laboratory for discussions presented throughout this document.

As part of the Activation Protocol, the backup (supporting) laboratory is contacted and discussion initiated about the issues present at the requesting laboratory, scope of services that will be needed, and likely duration of the service need. The supporting laboratory assesses its capacity relative to the scope of services needed and the duration of the service request and makes a determination if it can, or cannot support the requesting laboratory.

As an alternative the requesting laboratory can pursue use of other laboratories as backup in the event that the identified primary backup lab cannot support.

The primary backup laboratory also can access, at its discretion any backup plan or its own to accomplish activation, as long as it notifies the requestor of its intention. The primary backup lab will assure that any backup partner it proposes to use can meet its (the primary laboratory) quality control requirements.

Requesting Lab Sample Receiving
Significant terminology/concepts presented here include:

• Sample Receipt Contingency Plan – The strategy a laboratory has for reconstitution of its sample receiving capacity in an alternate location. The contingency plan should include those items needed for completion of data entry; sample splitting, storage and packaging; as well as capability to scan demographic elements of blood spot cards (BSC) and internet connectivity to allow for emailing scanned images to the supporting lab or alternately, dedicated facsimile (fax) phone line can be considered so that demographic elements of BSC can be faxed to the supporting laboratory. This contingency plan can be developed as a protocol of the laboratory’s larger contingency planning. This plan should address any issues relating to HIPAA compliance including data encryption software utilized.

Once the decision to activate backup services is made, the need for activation of the Sample Receipt Contingency Plan is considered and if relocation is required, this information is provided to the providers of blood spot cards and/or to the courier employed for transferring of samples from clients to the laboratory. The need to relocate sample receiving operations is also provided to the supporting laboratory, however there is minimal impact perceived for the supporting laboratory.
If it is desirable on the part of the requesting laboratory, splitting of samples can be undertaken but only if impact to the processing of samples by the supporting laboratory. The reasoning for potential splitting can be any number of issues including the desire to retain a portion of sample at the originating laboratory as a contingency for loss, maintenance of possession for quality assurance purposes, etc. Any consideration of the need for split samples on the part of the requesting laboratory will be secondary to the need for sample volume on the part of the supporting laboratory. The desire for retention of split samples on the part of the requesting laboratory is point to be negotiated as part of developing an Activation Protocol. As part of the Activation Protocol development is the negotiation between the parties on the minimally acceptable sample volume on the part of the supporting laboratory.

Once activation protocols are initiated, the requesting (impacted) sample receiving operations will initiate the process of demographic data scanning with emailing of images to the supporting laboratory’s sample receiving to allow for sample logging and accessioning into the supporting laboratory’s information management system (LIMS). Alternatively, the requesting laboratory personnel can remotely accession data into the supporting LIMS, if that system has the capacity for this and the supporting laboratory has requested and approved this support.

The requesting laboratory may maintain demographic data accessioning processes into its own LIMS for the duration of the activation, however the process of providing demographic data to the supporting laboratory becomes a priority of the requesting laboratory over any maintenance of demographic accessioning within the requesting laboratory. The requesting laboratory will reassign personnel from the areas where capacity has been lost to the sample receiving and accessioning functional areas to address any surge-related impacts of activation.

Additionally, the requesting laboratory will offer personnel to enhance the supporting laboratory’s capacity if so requested by the supporting laboratory. This need should be considered when developing the Activation Protocol, as well as the development of personnel in the entry of requesting lab data into the supporting laboratory’s LIMS.

**Samples Received at Supporting Lab**

Significant terminology/concepts presented here include:

- **Initial Activation Sample Surge** – each potential requesting laboratory presents a differing volume of samples that will flow to the supporting laboratory upon activation of this plan. That volume will include:
  - Volume of backed up samples received but not processed by the requesting laboratory in the period leading up to activation decision;
  - Volume of sample received, processed, but not yet analyzed and reported by the requesting laboratory in the period leading up to activation decision; and
  - Volume of sample received, processed, analyzed, but questionable for acceptability due to potential lost capacity for some period leading up to activation decision.
- **Ongoing Activation Sample Surge** – the normal daily volume seen by the requesting laboratory that will pass to the supporting laboratory during period of activation.
With respect to impact upon the supporting laboratory’s sample receiving under activation, the supporting laboratory will consider this an extraordinary sample surge event. The extent of impact will be dependent upon the respective requesting laboratory’s Activation Protocol that should include the Initial and Ongoing Activation Sample Surge.

Each respective requesting laboratory’s Activation Protocol will be reviewed as it is being developed for the following considerations:

- Does the Initial Activation Sample Surge represent an unmanageable surge issue for the supporting laboratory?
- Would the Initial Activation Sample Surge best be addressed by internal staff, by use of temporary hired staff, by use of temporary support from the requesting laboratory, or some combination of these approaches?
- Would the Ongoing Activation Sample Surge best be addressed by internal staff, by use of temporary hired staff, by use of temporary support from the requesting laboratory, or some combination of these approaches?
- Would use of temporary support from the requesting laboratory be a good approach to allow for internal staff and/or temporary hire staff to get up to speed on entry of Ongoing Activation Sample Surge?
- Does support LIMS allow for remote entry of demographic data and if so would support offer best be handled from the requesting laboratory facilities (minimizing surge entry space demands)?

The supporting laboratory will negotiate these considerations with each requesting laboratory as part of the activation-phase discussions. The supporting laboratory will review each requesting laboratory’s Activation Protocol and provide feedback on issues it identifies with these protocols. The supporting laboratory will incorporate the requesting programs’ Activation Protocols into its surge contingency planning.

**Supporting Laboratory Services**

The supporting laboratory will perform its standard services (and existing list of disorders without further modification) and report results based upon it existing algorithms. It will be the requesting laboratory’s responsibility to communicate any variance its existing services at the time Activation Protocol is undertaken.

Where indicated, reanalysis will be performed or resubmission of sample will be communicated to the requesting laboratory to communicate to birthing center or physician of record.

**Integration of Results from Supporting Lab back to Requesting Lab and Follow-up**

When completed, the supporting laboratory will report results on its standard forms to the requesting laboratory for handling as normal by the requesting program. Contingencies should be developed by the requesting laboratories on alternate venues and approaches to reconciling incoming results with the requesting LIMS. These contingencies are to consider loss of the laboratory’s dedicated space for results review and LIMS entry when and if that space is rendered unusable.
Contingency planning should also take into consideration the redirection of labor or procurement of temporary support for transfer of supporting laboratory reports to the requesting LIMS. Alternately, the requesting program could choose to report to interested parties using the supporting laboratory reports. If this option is pursued, the supporting laboratory should be notified, in case they choose to modify the forms for external reporting. Issues here might include desire on the supporting lab’s part to replace contact information to the requesting program so that fielding of questions is routed to the requesting program.

Sample Handling After Reporting
The supporting laboratory will negotiate with each requesting program on the final disposition of samples submitted by a requesting state. As the requirements on sample disposition may vary for each requesting program, the supporting laboratory may initiate or develop a different approach for each requesting program but likely the possible solutions will fall into once of two categories:

- Return samples to the requesting laboratory within so many days of acceptance of the sample results report by the requesting laboratory, or
- Destruction of the sample within so many days of the acceptance of the sample results report by the requesting laboratory.

A potential third disposition of the samples is possible, namely that of storage by the supporting state per established standard of that lab. If the requesting lab has protocols relating to long term storage of the samples, the requesting lab will make these known and negotiate specific handling approach with the supporting laboratory during development of the requesting program’s Activation Protocol.

Roles and Responsibilities

Requesting Programs
Vital elements necessary for action under this plan that are the responsibility of the requesting program include:

- Following the Activation Threshold’s deadline for activation decision making.
- Following the Activation Protocol developed before the emergency or developing one “on the fly” as the emergency begins.
- Notifying the support program (the NBS Backup Laboratory) and reviewing the incident-specific details and any changes from the situational description of the Activation protocol.
- Being prepared to execute an alternative in the event that the identified Backup Laboratory is unable to take the samples.
- Making the identified sample receiving venue operational if that capacity / area is unavailable in the incident.
- Finalizing Public Service Announcement (PSA) templates to the specific situation and providing these to the identified points of contact among endusers/clientele.
• Executing contingency plans for remote results processing and follow-up where the capacity / space to do this at the laboratory has been lost. This includes remote imaging of the LIMS and sample reporting systems.
• Have ready, and if necessary implement contingency support of the supporting laboratory for sample receiving/accessioning and any other potential functionality for the duration of the Backup Laboratory’s surge, if requested by the Backup Laboratory.
• Notification of changes in the situation where these impact the volume into the Backup Laboratory.
• Utilize, if necessary support offers from Plan Administrators or others. This could include identification of alternate supplies, couriers, data processing personnel and other backup laboratory capacity. This support would come as a voluntary effort on these people/parties.

**Supporting Programs**

Vital elements necessary for action under this plan that are the responsibility of the supporting program include:

• Discussing the situation with the requesting program (impacted laboratory), ensuring discussion include any changes from the situational elements of the Activation Protocol developed prior to the incident. If this has not been developed, to support the requestor by reviewing and providing comment on Activation Protocol developed by them “on the fly”.
• Stand up surge capacity in sample receiving and data entry/accessioning sufficient to process the Initial Activation Sample Surge sample load. Note any offer that exists from the requesting program or other, non-impacted programs that have worked with the supporting program to provide temporary support for the surge.
• Review samples as received and results as developed for acceptability, routing any resampling request to the impacted laboratory’s emergency sample receiving and results review elements. Note that these elements may be temporarily located remote to the impacted laboratory and as such may have new phone numbers and fax lines.
• Discuss as soon as identified, any issues with sample processing and analysis that could impact the requesting programs sample turn around time.
• Handle all requesting program samples in the manner negotiated at the time of activation.

**Plan Administrators/Keepers**

Plan administrators do not represent an official public health authority and do not have an official role in response phase operations. However the nature of SERC (http://southeastgenetics.org) is that the plan administrators have an interest in aiding impacted programs and could be asked to support in coordinating support from other SERC NBS programs and alternate backup laboratory identification if the primary backup laboratory is unable to accept samples from an impacted laboratory.

Other similarly capable supporters include the Association of Public Health Laboratories, Emergency Preparedness Workgroup (http://southeastgenetics.org/committees.php/10/general/Emergency_Preparedness_Workgroup)
and the National Coordinating Center for the Genetic and Newborn Screening (http://www.nccrcg.org)

All groups mentioned here would be acting in the capacity of voluntary organizations active in disaster (VOAD). Participation would come at the request of either a requesting or supporting program.

**Plan Maintenance**

**Owner of This Plan (Plan Keepers)**

For the initial 12 months following approval of this plan, the plan administrators will be:

- **SouthEast Regional NBS & Genetics Collaborative:**
  - Tim Wood, Laboratory Performance Workgroup Leader
  - Hans Andersson, Emergency Preparedness Workgroup Leader

- **The Florida Department of Health, Newborn Screening Program:**
  - Jasmin Torres, Chemist Administrator, Florida NBS Laboratory

The Plan Owner will be responsible for the process described here in plan maintenance as well as management of the Implementation Plan (Appendix C).

**Revision of This Plan**

The Implementation Plan addresses the activities of the first six months following adoption of the plan by any identified parties. Adoption is implied by completion of Table B-1 in Appendix B.

Revision of the plan will be initiated 3 months prior to the first anniversary of the plans publication. Revision will be managed the SERC Lab and EP Workgroups and will include collection of any lessons learned from exercise(s) or activations of the plan. Revision will be accomplished by a Core Planning Team composed of plan administrators and at least one representative from each SERC NBS program.

Other items that are under consideration for the next version of this document include identification of an alternate backup laboratory, resource mapping to develop standardized data management teams, etc.

**Training Relative to This Plan**

Several possible training activities are possible relative to this plan, including:
<table>
<thead>
<tr>
<th>TITLE</th>
<th>DESCRIPTION</th>
<th>TARGET AUDIENCE</th>
</tr>
</thead>
<tbody>
<tr>
<td>SERC NBS Backup Plan Roll-out</td>
<td>Awareness focused review of plan, the implementation tools identified and its implementation plan. Duration likely to be 2 – 4 hours. Possibly remote delivery or direct delivery.</td>
<td>NBS program / laboratory management / follow-up personnel / with modification, end-users/clientele.</td>
</tr>
<tr>
<td>Data Entry / LIMS Training</td>
<td>Training to potential emergency support personnel on the data entry / accessioning functionality of the supporting (backup) laboratory’s LIMS.</td>
<td>Any qualified and experienced data entry personnel at a potential support laboratory. Represents reserve capacity for the backup laboratory that does not necessarily have to impact the requesting laboratory if personnel are drawn from non-impacted SERC NBS laboratories.</td>
</tr>
</tbody>
</table>

**Table 5 - Possible Training Courses**

**Exercising of This Plan**

Program using this document recognize the need for an incrementally progressive exercise program to validate the plan and its functional elements, as well as to capture recommendations for improvement. The Homeland Security Exercise and Evaluation Program (HSEEP) methodology is recognized as the approach that will be employed for the maintenance of this plan.

Potential topics for exercises include:

- Tabletop exercise reviewing the activation protocol(s) of one or more states.
- Functional exercise testing specific elements of the CONOPS, including sample receiving/shipment, data entry/accessioning, sample analysis & reporting, PSA development/use, etc.
- Full scale exercise where one or more laboratories activate multiple functional elements of this plan in cooperation with activation of the identified backup laboratory.

For the first version of the plan, a tabletop exercise will be conducted on at least one activation protocol to explore the content and seek improvement early in the implementation plan period and aid other states in development of their activation protocols. That exercise will take place at the SERC Annual Conference in mid-July 2013.

**Capturing Improvement Recommendations**

The Plan Administrators / Plan Keepers will initiate a program improvement process including use of the Corrective Actions Matrix/Improvement Plan. This matrix/plan will be utilized early in the revision process.
Authorities

<table>
<thead>
<tr>
<th>State</th>
<th>Citation (Law; Regulation – if known)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Georgia</td>
<td>OCGA 31-12-6 &amp; 31-12-7; Chapter 290-5-24</td>
</tr>
<tr>
<td>Florida</td>
<td>Florida Statutes: § 383.14</td>
</tr>
<tr>
<td>Louisiana</td>
<td>LAC 48, Part V, Subpart 19, Chapter 63 §6303</td>
</tr>
<tr>
<td>North Carolina</td>
<td>NCGS 130A-125</td>
</tr>
<tr>
<td>South Carolina</td>
<td>SCC 44-37-30; Regulation 61-80 (SC DHEC)</td>
</tr>
<tr>
<td>Tennessee</td>
<td>TCA 68-5-4</td>
</tr>
</tbody>
</table>

References


**Newborn Screening Contingency Plan (CONPLAN)**, Department of Health and Human Services, July 2010.

**Memorandum of Agreement Between the Florida Department of Health, Newborn Screening Program and the Texas Department of State Health Services, Newborn Screening Program Regarding the Continuity of Operations Plan (COOP)**, FDH and DSHS, signed February 2013.
Appendix A – Memorandum of Understanding
Memorandum of Agreement
Between
[STATE A – NBS PROGRAM TITLE]
And
The Florida Department of Health, Newborn Screening Program
Regarding
The Continuity of Operations Plan (COOP)

THIS MEMORANDUM OF AGREEMENT is entered into between [STATE A – NBS PROGRAM TITLE], located at [ADDRESS OF STATE A LAB] and the Florida Department of Health, Newborn Screening Program, located at 1217 Pearl Street, Jacksonville, Florida 32202.

I) Scope of Services
   A) Program Definitions.
      1) Newborn Screening (NBS) – One or more tests to identify a newborn that may be at risk of having a disorder on the screening panel of either state but for purposes of defining services offered, the screening panel offered is the State of Florida’s.
      2) NBS Specimen – Dried blood spot (DBS) sample used for NBS testing that consists of drops of blood collected on a specialized filter paper collection devise. Other equivalent terms used include blood spot card, dried blood spot specimen, or blood spot.
      3) NBS Data (Data) – Includes demographic information received on the NBS specimen collection form, the NBS test results, diagnosis and follow-up case data compiled as part of the clinical coordination of care of individual children (i.e. with positive NBS test results).
      4) Unsatisfactory Specimen – A specimen that cannot be tested for one or more conditions.

   B) [STATE A] Specific Definitions.
      1) [STATE A] NBS Follow-up Program – The statewide program administered by [STATE A – FOLLOW-UP ADMINISTERING ENTITY NAME] by which all newborns with abnormal NBS screening test results are tracked and referred for appropriate follow-up and treatment if necessary.
      2) Presumptive Positive NBS Result – A value outside the anticipated range set for each test, indicating the importance of promptly referring the baby for evaluation, and diagnostic and confirmatory testing.
      3) Borderline NBS Result – A test result that is outside of the expected range of testing established for a particular condition, which the [STATE A] NBS Follow-up Program protocol requests a repeat specimen be collected.
      4) Confirmation Testing – Testing that must be performed on any infant identified through the [STATE A] NBS Follow-up Program with a presumptive positive NBS result, in order to diagnose the infant with a disorder or as normal.
5) [STATE A CONTRACTED FOLLOW-UP CENTERS] – A facility designated by [STATE A FOLLOW-UP ADMINISTRATIVE ENTITY] through a contract or memorandum of agreement as having a program specifically designed to provide evaluation, diagnostic and treatment services as well as counseling and education to families of newborns with presumptive positive NBS results.

C) Florida Specific Definitions.
   1) Florida NBS Follow-up Program – The statewide program administered by Children’s Medical Services by which all newborns with abnormal NBS screening test results are tracked and referred for appropriate follow-up and treatment if necessary. This level of service support for [STATE A] is not offered under this agreement. It is mentioned here as Florida NBS Follow-up Program is owner of protocols that cause actions to be taken by Florida’s NBS lab, as noted below. Florida’s NBS Follow-up Program may also be in contact with [STATE A] follow-up services to assure that presumptive positives are being noted by [STATE A] follow-up services.
   2) Presumptive Positive NBS Result – A value outside the anticipated range set for each test, indicating the importance of promptly referring the baby to [STATE A]’s follow-up services for evaluation, and diagnostic and confirmatory testing. Services identified in this agreement include identification of presumptive positive NBS results by Florida’s NBS Lab to [STATE A]’s NBS lab and follow-up services.
   3) Borderline NBS Result – A test result that is outside of the expected range of testing established for a particular condition, which the Florida NBS Follow-up Program protocol requests a repeat specimen be collected.

D) General Description.
   1) General Statement: The purpose of this Agreement is to provide a Continuity of Operations Plan (COOP) framework and initial scope of work in the event that [STATE A] NBS laboratory is unable to perform its statutory duties relating to laboratory testing due to any naturally occurring or man-made disaster or catastrophic information technology failure. The ability to exercise the plan is also covered by this agreement.
   2) Authority:
      a. [STATE A REGULATORY CITATION]
      b. The Florida Department of Health, Newborn Screening Program (hereinafter referred to as “Florida”) is required to perform NBS in accordance with § 383.14, Florida Statutes.

II) Terms
   This Agreement shall be effective from the date of signed agreement through five years from that date.

   A) Renewal.
   At the end of the five-year term a review, update and a written renewal will be processed if the need for the Agreement remains and the parties so agree.
B) Termination at Will.
   Either party may unilaterally terminate this Agreement with advance 30-day written notice. This contract may be terminated by either party, without cause, upon such written notice of the other party. Said notice shall be delivered by certified mail, return receipt requested, or in person with proof of delivery.

III) Request for Assistance
A) Emergency or Disaster.
   If [STATE A] NBS program services are threatened with impact from an impending or existing emergency or disaster either natural or man-made that precludes [STATE A]’s laboratories from conducting analysis of NBS tests, [STATE A] may request assistance from Florida’s NBS Laboratories under this MOA in order for [STATE A] to accomplish its statutory duties.

B) Exercise.
   Either party may request that a test run (COOP exercise) of this MOA be executed to validate or identify gaps in the plan, provided that no patient record, patient identifying information or information that meets the definition of “protected health information”, at 45 CFR § 160.103 will be provided as part of a test under this paragraph, without the express written consent of the patient or patient’s legal representative.

IV) Scope of Work and Service Tasks
   Exact services (participation level or activities) of the parties will be determined at the time of activation of this MOA based upon the extent of assistance requested. [STATE A] shall notify Florida in writing of its request for assistance and shall identify in such notice the type of assistance required. If the event is an exercise initiated at Florida’s request, Florida will make that request in writing.

A) Specimen transportation/delivery is the responsibility of [STATE A].
B) Florida NBS laboratories will provide the following services on an as-needed basis:
   1. Receive NBS specimens and provide testing of all disorders tested in Florida at the time of the event. List of disorders can be found at: http://www.doh.state.fl.us/cms/NewbornScreening/nbscreen-disorder.html.
   2. Report laboratory results as detailed at the time of the emergency.

V) Confidentiality
   A) All activities taken as part of this Agreement involving any specimens or data which contains any information that directly or indirectly allows the linkage of a blood spot or data derived from the NBS blood spot back to the child or the parents of the child from which the specimen was collected will adhere to the federal Health Insurance Portability and Accountability Act (HIPAA) and the regulations issued by the United States Department of Health and Human
Services under the Act, including the HIPAA security and privacy regulations (45 CFR Parts 160, 162 and 164), and will also comply with the applicable state confidentiality laws concerning those specimens/data.

B) Specimens and data will only be used for purposes of NBS tests and follow-up. A state conducting activities under this MOA on behalf of other states will not allow any research to be conducted on the specimens and/or associated data, not will it allow any external entity to utilize the specimens for quality assurance/quality control purposes.

C) All specimens, demographic entry forms and data will be returned to [STATE A] sample receiving. The timeline for return will be determined during or near the end of the event period.

VI) Reimbursement
[STATE A] bears any and all fiscal responsibility for the cost of services provided to it under this Agreement. It is the responsibility of [STATE A] to apply for all state and federal aid reasonably available to it.

Unless otherwise specified in this Agreement, the reimbursement will be set at the current market value to cover the services provided during the event.

Details of reimbursement will be determined at the time of the event.

VII) Subcontracts
Florida shall not subcontract for the services provided under this contract without the express advanced written approval of [STATE A].

VIII) Liability
Each party agrees to be responsible for the negligence of its employees when acting within the scope of their employment, and agrees to be liable for damages resulting from said negligence to the extent permitted by law. Nothing herein is intended to serve as a waiver of sovereign immunity by any provider to whom sovereign immunity may be applicable. Nothing herein shall be construed as consent by a state agency or political subdivision of the State of [STATE A] or the State of Florida to be sued in any manner arising out of this Agreement.

IX) Modification
Neither this Agreement, nor any provision hereof, may be amended or otherwise modified, except by a written instrument signed by all parties hereto.

X) Notice
Any notices given by either party to the other party under this Agreement shall be in writing. Notice will be provided to the following addressed.

[STATE A]: [STATE A HEALTH AUTHORITY NAME]
[STATE A NBS PROGRAM NAME]
[STATE A NBS LAB ADDRESS]
XII) Authorizing Signatures

IN WITNESS THEREOF, the parties hereto have caused this Agreement to be executed by their officials thereunto duly authorized.

STATE OF [STATE A] [STATE A HEALTH AUTHORITY NAME]  
SIGNED

By: __________________________  
Name: ________________________  
Title: _________________________  
Date: _________________________

STATE OF FLORIDA Florida Department of Health  
SIGNED

By: __________________________  
Name: ________________________  
Title: _________________________  
Date: _________________________
Appendix B – Participant Points of Contact
### Table B-1: Authorized Points of Contact

<table>
<thead>
<tr>
<th>Organization</th>
<th>Point of Contact</th>
<th>How to Reach</th>
</tr>
</thead>
<tbody>
<tr>
<td>Florida NBS Laboratory</td>
<td>Jasmin Torres</td>
<td>904-791-1648</td>
</tr>
<tr>
<td></td>
<td></td>
<td><a href="mailto:Jasmin_Torres@doh.state.fl.us">Jasmin_Torres@doh.state.fl.us</a></td>
</tr>
<tr>
<td>Georgia NBS Laboratory</td>
<td>Arthur F. Hagar</td>
<td>404-327-6800</td>
</tr>
<tr>
<td></td>
<td></td>
<td><a href="mailto:afhagar@dhr.state.ga.us">afhagar@dhr.state.ga.us</a></td>
</tr>
<tr>
<td>Georgia Follow-Up</td>
<td>Johanna Pringle</td>
<td>TBD</td>
</tr>
<tr>
<td>Louisiana NBS Laboratory</td>
<td>Terry Crockett</td>
<td>504-219-4696</td>
</tr>
<tr>
<td></td>
<td></td>
<td><a href="mailto:terry.crockett@la.gov">terry.crockett@la.gov</a></td>
</tr>
<tr>
<td>Louisiana Follow-Up</td>
<td>Cheryl Harris</td>
<td>504-568-8254</td>
</tr>
<tr>
<td></td>
<td></td>
<td><a href="mailto:cheryl.harris@la.gov">cheryl.harris@la.gov</a></td>
</tr>
<tr>
<td>North Carolina NBS Laboratory</td>
<td>Shu Chaing</td>
<td>919-807-8880</td>
</tr>
<tr>
<td></td>
<td></td>
<td><a href="mailto:Shu.Chaing@dhhs.nc.gov">Shu.Chaing@dhhs.nc.gov</a></td>
</tr>
<tr>
<td>North Carolina Follow-Up</td>
<td>TBD</td>
<td>TBD</td>
</tr>
<tr>
<td>South Carolina NBS Laboratory</td>
<td>Sandi Hall</td>
<td>Phone Number – TBD</td>
</tr>
<tr>
<td>South Carolina Follow-Up</td>
<td>TBD</td>
<td><a href="mailto:hallss@dhec.sc.gov">hallss@dhec.sc.gov</a></td>
</tr>
<tr>
<td>Tennessee NBS Laboratory</td>
<td>Chris McKeever</td>
<td>615-262-6352</td>
</tr>
<tr>
<td></td>
<td></td>
<td><a href="mailto:chris.mckeever@tn.gov">chris.mckeever@tn.gov</a></td>
</tr>
<tr>
<td>Tennessee Follow-Up</td>
<td>Mitzi Lamberth</td>
<td>615-532-8512</td>
</tr>
<tr>
<td></td>
<td></td>
<td><a href="mailto:mitzi.lamberth@tn.gov">mitzi.lamberth@tn.gov</a></td>
</tr>
</tbody>
</table>

1 Florida’s NBS program is the primary backup service provider as defined in this plan.
2 Georgia NBS Follow-up services utilizes Emory University as a partner.
Appendix C – Implementation Plan
**Requesting Programs**

Activation Phase-related actions to be accomplished prior to first initiation (target date is within the first six months following publication of this plan) include:

1. Review this plan, note issues and seek revision to address issues.
2. Determine the lab-specific Activation Threshold, down to disorder specific details where applicable.
3. Review potential need for backup with management (lab, public health authority, emergency management agency, and any other procurement authorizing entities), develop list of activation steps necessary.
4. Contact potential supporting program(s) and review elements necessary for developing Activation Protocol. Review recommended of supporting program actions relative to this phase prior to initiating discussions.
5. Once negotiations are complete, develop Activation Protocol, include Activation Threshold, relevant points of contact, and specific steps to rapidly initiate backup.
6. Share Activation Protocol with lab/department contingency planners, as well as with keepers of this plan for inclusion in next version of emergency plans.

Sample Receiving Phase-related actions to be accomplished prior to first initiation (target date is within the first six months following publication of this plan) include:

1. Review and develop a Sample Receiving Contingency Plan (or protocol, for the existing laboratory contingency plan).
2. Identify an alternate venue for sample receiving remote to the location of the existing sample receiving site.
3. Prepare a cache of supplies that can be dedicated to the alternate sample receiving site. Note: this may require capital funding and may not be actionable within the first six months but should become an action item for funding under the next fiscal cycle. Also note: once cache is developed, it should be stored remotely from the primary sample receiving location and routinely reviewed for replacement of perishable items (including batteries that might power equipment).
4. Prepare a plan for training of personnel on the supporting laboratory’s LIMS systems. Note: action on this plan may require capital planning and stretch into subsequent fiscal cycle. Also note: this plan should consider the possibility of remote accessing support laboratory’s LIMS and the deployment of personnel to the support laboratory to aid in addressing surge issues of activation. These considerations should be made in cooperation with the supporting laboratory and its plans for dealing with a surge.
5. Prepare a plan for eventual validation of the Sample Receiving Contingency Plan/Protocol through exercise development and conduct.

Sample Analysis Phase-related actions to be accomplished prior to first initiation (target date is within the first six months following publication of this plan) include:

1. Develop public service announcement (PSA) templates that will be available when activation occurs. These should indicate alternative sample receiving location, if applicable. These should indicate who will be performing the analyses, what changes will happen to the disorder list (if applicable) and other relevant changes in services offered.
2. Review supporting laboratory’s quality control flow chart when developed by the supporting laboratory. Edit or validate and when valid, append to the Activation Protocol.

3. Act on any revision of the supporting laboratory’s quality flow chart when developed and review the changes in services offered by the supporting laboratory. When validates, replace flow chart in the Activation Protocol and revise any PSA’s developed as needed.

Results Handling Phase-related actions to be accomplished prior to first initiation (target date is within the first six months following publication of this plan) include:

1. Negotiate the approach that sample results from the supporting laboratory will be handled, including possibilities of transcription of results into the requesting laboratory’s LIMS, direct transfer of data from the supporting LIMS to the requesting LIMS (if possible), or modification of the supporting lab reports for direct use to requesting laboratory customers/end-users. This decision and applicable reporting templates, data entry protocols, etc. should be included with the Activation Protocol.

2. Document any changes to the approach chosen and included originally with the Activation Protocol and replace appended documentation as applicable.

Sample Handling Phase-related actions to be accomplished prior to first initiation (target date is within the first six months following publication of this plan) include:

1. Negotiate the approach to long-term sample storage with the supporting laboratory.

   - Document the approach and add to the Activation Protocol.

2. If any changes to this approach developed, document the new approach and replace relevant text in the Activation Protocol.

Supporting Programs

Activation Phase-related actions to be accomplished prior to first initiation (target date is within the first six months following publication of this plan) include:

1. Participate in any discussions requested by potential requesting programs, providing necessary point of contact information, sample receiving, sample reporting process and account receiving requirements on your part.

2. Review and provide comment on requestor requirements on procurement, sample splitting, sample disposition and results reporting requirements.

3. Negotiate resolution of any issues identified in review of requestor requirements.

4. Review Activation Protocol developed by requesting programs, complete resolution of any issues identified and confirm with requestor your ability to meet requirements.

5. Report to plan keepers the status of negotiations (initiated, underway or completed).

Sample Receiving Phase-related actions to be accomplished prior to first initiation (target date is within the first six months following publication of this plan) include:

1. Support the development of a Sample Receiving Contingency Plan/Protocol on the part of any potential requestor laboratories through discussion of issues and provision of recommendations (if prompted by the requestors).

2. Incorporate any alternate sample-receiving venue location information into plans for sample receiving under activation plans. This is intended to mainly be an “for your information” only type activity.
3. Discuss requestor plans to train its personnel in data entry on your LIMS systems, whether your system allows for remote entry or whether you might need short-term support for data accessioning during a surge. Note: requestor laboratories may wish to develop this capacity as a contingency of your strategy and it is recommended that you consider this offer regardless of the strategy developed. Also action on requestor plans may require capital budgetary planning that will make action on this item happen outside the six-month window.

4. Discuss requestor plans to test their contingency plan through exercises and whether or not your participation will be required (such as receiving dummy data from a requesting laboratory and rolling this into a test of your systems to receive and process this data).

5. Incorporate any necessary changes in your contingency plans relative to Initial Activation Sample Surge and Ongoing Activation Sample Surge for each requestor program.

Sample Analysis Phase-related actions to be accomplished prior to first initiation (target date is within the first six months following publication of this plan) include:

1. Finalize quality control review flow chart for each requesting laboratory. These flow charts should indicate what actions are required where non-conformity is identified. These flow charts can be combined where the issues and resolution approach is identical for two or more requesting laboratories.

2. Share these flow charts with the respective requesting program for review and when validated, append to supporting laboratory’s contingency planning documents.

3. Revise these flow charts whenever changes in services offered are modified. Notify requesting laboratories of the change and share/act as described in #2.

Results Handling Phase-related actions to be accomplished prior to first initiation (target date is within the first six months following publication of this plan) include:

1. Negotiate with each requesting program the approach that sample results from the supporting laboratory will be handled, including possibilities of transcription of results into the requesting laboratory’s LIMS, direct transfer of data from the supporting LIMS to the requesting LIMS (if possible), or modification of the supporting lab reports for direct use to requesting laboratory customers/end-users. The approach and applicable reporting templates, data entry protocols, etc. should vary by each program and documentation should be maintained with other activation data in existing contingency planning of the supporting laboratory.

2. Document any changes to the approach once activation is underway and replace appended documentation as applicable.

Sample Handling Phase-related actions to be accomplished prior to first initiation (target date is within the first six months following publication of this plan) include:

1. Negotiate the approach to long-term sample storage with each requesting program. Document the approach and add to existing supporting laboratory contingency plans.

2. If any changes to this approach developed, document the new approach and replace relevant text in the contingency plans.

**Plan Keepers**

Activation Phase-related actions to be accomplished during first six months following publication of this plan) include:
1. Maintain contact with all states/territories.
2. Determine status of negotiations.
5. Report summary of Activation Protocols to all parties of this plan.
6. Use summary in revision of plan.
7. Compile items collected as regional best practice examples.

Sample Receiving Phase-related actions to be accomplished during first six months following publication of this plan) include:

1. Collect information on requestors and supporting laboratory development of sample receiving contingency plans/protocols.
2. Collect information on requestors and supporting laboratory plans to train personnel on sample receiving plans/protocols.
3. Collect information on requestors and supporting laboratory plans to exercise/validate sample receiving plans/protocols.
4. Collect information on supporting laboratory’s contingency planning relative to all requestor Initial and Ongoing Activation Sample Surge data.
5. Support inter-laboratory training and exercise activities at the regional level.
6. Report findings in this topic area to the region as a whole.
7. Compile items collected as regional best practice examples.

Sample Analysis Phase-related actions to be accomplished during first six months following publication of this plan) include:

1. Collect requesting laboratory public service announcement templates as developed.
2. Collect supporting laboratory quality control flow charts as developed.
3. Summarize progress made with regard to these items and report back to the region as a whole.
4. Compile items collected as regional best practice examples.

Results Handling Phase-related actions to be accomplished during first six months following publication of this plan) include:

1. Collect information on the negotiations undertaken between the supporting lab and each of the potential requesting programs relating to the approach to sample results reporting. Note that there may be different approaches for each requesting program.
2. Collect any applicable reporting templates, data entry protocols, etc – these are potential regional best practice examples.
3. Prepare a summary report of progress on this topic for the region.

Sample Handling Phase-related actions to be accomplished during first six months following publication of this plan) include:

1. Collect information on the negotiations undertaken between the supporting lab and each of the potential requesting programs relating to sample disposition. Note that there may be different approaches for each requesting program.
2. Collect any applicable documents – these are potential regional best practice examples.
3. Prepare a summary report of progress on this topic for the region.