As the construction on the new facility for the State Laboratory of Public Health (SLPH) and the Office of the Chief Medical Examiner (OCME) continues steadily, I have been thinking about change. A famous quote proclaims that the only sure things are death and taxes. I believe change is, paradoxically, a constant as well. While some changes are welcome and easier to manage, others are less welcome and harder to manage. I wanted to share some helpful hints I found about managing change from a document entitled “Managing Change: How to Manage Change in an Organization” published by the Government Office for the Southwest and found at [www.oursouthwest.com/SusBus/mggchange.pdf](http://www.oursouthwest.com/SusBus/mggchange.pdf).

There are four essential elements for change to be successful in an organization, and they are:

- Commitment to change by senior management.
- Clear, shared vision that benefits the whole organization.
- Capacity for change, including time and financial support.
- Plan, Do, Check, Act process followed while keeping lines of communication open.

Leslie A. Wolf, PhD, HCLD (ABB)
Laboratory Director

**MISSION statement**

The State Laboratory of Public Health provides certain medical and environmental laboratory services (testing, consultation and training) to public and private health provider organizations responsible for the promotion, protection and assurance of the health of North Carolina citizens.

http://slph.ncpublichealth.com
Commitment to Change
It is important to identify the reasons for change—are they internally driven, externally driven, or both? Everyone needs to understand the fundamental reasons for change, and senior management must be consistent in backing up their words with actions.

For the new facility, the reasons for change were both internally and externally driven. The Bath Building was constructed during a time when many laboratory tests were manual and reflected public health concerns of the early 1970s. As a result, the current facility limits the types of testing or amount of testing that can be performed to meet the needs of our current decade. Our partners in public health frequently communicate the need for new tests, advanced methods or increased test volume that can’t be met in the Bath Building.

Clear, Shared Vision
Hand in hand with a commitment to change is a clear vision of what the change will look like down the road. Change takes many of us out of our comfort zone and creates stress. Communication about the benefits that will result is critical, as is implementing the change at all levels. How is this accomplished? By understanding what motivates people in the organization and, in turn, by motivating staff to join the effort. Most of us are motivated by pride, happiness, responsibility, recognition, security, and money, although each of us may rank these factors in varying orders of importance.

One method SLPH has used to communicate the vision for the new facility is to post the construction plans in a designated hallway, as well as photos taken during frequent visits, to show the building progress. The benefits of the new facility have also been communicated, in which a state-of-the-art facility will have many safety features, natural light, flexible space, and new opportunities to increase efficiencies and collaborations.

Capacity for Change
Quite simply put, capacity for change equates to resources, the most important of which are staff time and funding. For success, these key resources need to be identified at the beginning of the change process, not in the middle or the end. Many times, these are resources that are in short supply in government institutions, and SLPH staff members wear many hats to accomplish the mission of SLPH.

For the new facility project, beginning with a feasibility study in 2004 and continuing to the present day, SLPH managers, supervisors and employees with an interest in the process have contributed greatly by communicating their needs, reviewing plans, and providing feedback so that the new facility meets the laboratory testing needs.

Action
For those of you involved in quality management, the process of “Plan, Do, Study, Act” is very familiar. After the Commitment, Clear Vision, and Capacity for Change elements are in place, then the action of implementing the change can begin. Of course, remembering that the process is a repeating cycle is important so that ongoing monitoring occurs and course adjustments are made as necessary. At this point, the role of the “cheerleader” is needed to keep the excitement, motivation and momentum of the project moving forward.

During the construction project, I have found that reviewing progress and consulting the drawings while providing feedback in a timely manner is challenging. Our process continues to evolve as we learn what has been effective and what has not, especially because there are so many stakeholders involved.

Is Change Management Working?
Finally, how do you know the process is being effective? Some of the questions you may hear from staff members that are cause for concern include the following:

- “Nobody told me about it…”
- “It will all change again next month…”
- “I’m keeping my head down this time…”
- “It’s not my job…”
- “If it’s such a good idea, why didn’t we do this last time…?”

It has also been shown time and time again that when employees take pride in their organization, performance improves. My hope is that SLPH staff members continue to take pride in our mission, and the time they have invested in planning the new facility, so that our performance continues to improve.

Submitted by:
Leslie A. Wolf, PhD, Laboratory Director,
NCSLPH
North Carolina’s Response to the Natural Disaster in Japan

The morning of March 11, 2011, began like most others in Japan; however, by afternoon the lives of most of Japan’s residents were changed forever.

An earthquake, with a magnitude of 8.9, hit off the coast of Japan and a massive 43-foot tsunami was created by the energy from this underwater quake. The tsunami damaged miles of coastline as well as inland areas, and nearly everything in the wake of this wave was destroyed. Fukushima Nuclear Power Plant resided within this vast area of destruction. The wave surpassed the 19-foot seawall around the power plant and flooded many floors, including the basement where the nuclear reactors were housed. The wave that hit the facility caused a complete power outage. Luckily, two of the reactors on Japan’s coast were already shut down for routine maintenance before the storm arrived. The remaining reactors were running on backup generators and batteries until they failed. Without sufficient water cooling, fuel rods in reactor cores started melting down, and nuclear fission by-products were released into gas and aqueous phases. The buildup of hydrogen gas pressure inside the reactor safety shell ultimately resulted in multiple explosions. Radioactive steam was released on the recommendation of Japanese officials to prevent further explosions. Several radioactive isotopes contained in this steam were of concern from this disaster: Iodine-131, Cesium-134, Cesium-137, and Strontium-90, all of which are by-products of nuclear fission.

The North Carolina State Laboratory of Public Health’s Environmental Radiation Unit routinely monitors air, surface water, ground water, rain precipitation, sediment, fish, vegetation, milk, and some foods. Following the radioactive release, the Division of Health and Human Services Radiation Protection Section increased their sample collection activities, a reprioritizing of samples occurred, and the Environmental Radiation Unit began increased monitoring of air, water, vegetation and milk samples. Raw milk is one of the first places radiation may be found due to ingestion pathways. The sampling of milk went from about three times a month to multiple times daily immediately following the disaster. The samples were tested by a gamma-ray spectrometer. This eight-hour test required the gamma-spec analyst to set up samples during the normal work day and then return to the laboratory in the evenings and on weekends to set up another round of analysis.

On March 21, 2011, the lab began finding hits of Iodine-131 in air samples. Cesium-134 and Cesium-137 were found in air filters and vegetation on March 22, 2011, and March 25, 2011, respectively. Iodine-131 has a half-life of eight days, so most will disappear in about two months. Cesium-137 has a half-life of thirty years, and therefore can affect human health for decades. Iodine-131 is typically not found in milk samples; however, it began showing up around March 28, 2011. Around the same time, positive samples were also found in rainwater. The graph shows when the radiation was initially found in the milk and rainfall samples, and how quickly it was gone. Essentially, North Carolina found results consistent with the rest of the nation. Of the radiation detected, nothing was flagged as dangerous levels to cause concern. On average, the positive samples were just above the baseline detection of the lab’s instruments. The last positive sample found that was attributed to Japan’s disaster was on May 5, 2011, in air filter samples. All of the results produced were submitted to the North Carolina Radiation Protection Section for interpretation. At this time, increased monitoring has ceased and routine monitoring has returned.

Submitted by:  
Michele Andrews  
Laboratory Certification  
Environmental Sciences
N.C. Public Health, 50 years ago...
Sept. 1961
State Board of Health Meeting 9/29/61

“Dr. Foard, Director, Epidemiology Division, reported on a food poisoning outbreak at Williamston which occurred on September 6, the first day of school. A dinner was given to the school children in one of the schools consisting of chicken salad, pimento cheese and a salad with dressing as the three principal foods. In addition, milk was served. Feeding started at 11:00 a.m. and by 3:00 p.m. thirty children were seriously ill and seven were hospitalized during that afternoon. Samples of the food served were obtained and sent to the State Laboratory. Only one of the foods – chicken salad – showed contamination which was by staphylococcus. An examination through culture taken of persons who prepared the food showed that the lady who prepared the chicken salad was infected (nose and throat) with staphylococci. Inadequate refrigeration, after preparation of the salad, increased the danger. All children have recovered and were reported to be back in school within a ten-day period.”

“Dr. Maddry, Acting Director, Laboratory Division, presented a written report on the custom built incubator developed by two employees in the Laboratory which has saved the State $2,000. After discussion, Dr. Bender moved that the Board express its commendation and appreciation for the excellent job done in constructing the incubator, and test tube holders, for the Laboratory Division which has resulted in considerable saving to the State.”

100 Years Ago....... The Early Development of County Health Departments

“The earliest record of a county appropriation for full time public health work is from Jefferson County, Kentucky, during the year 1908. In June 1911, Guilford County, North Carolina, and in July, Yakima County, Washington organized county health departments which have continued in operation without interruption since their establishment. Guilford was the first North Carolina County to employ a health officer full-time; here Dr. G.F. Ross took office on June 1, 1911, and was paid a salary of $2,500 per year which included all expenses. His work was mainly to combat hookworm disease and deal with other health problems in rural sections of the County. Robeson was the second North Carolina county to provide full-time health service when Dr. B.W. Page took up his duties on April 1, 1912, to continue the work against hookworm disease begun during the dispensary campaign.”

July 1, 1913 – Sampson, Durham, and New Hanover became full-time health department counties.

“As to expenditures, the Laboratory of Hygiene spent $10,000 for assistants, apparatus, and supplies; for administering the Pasteur treatment*; and for the distribution of diphtheria antitoxin.”

“Dr. Rankin (State Health Officer, Secretary & Treasurer of the NCBOH) then pointed out concrete examples of how the State’s investment in public health work pays large dividends. The Laboratory of Hygiene, for example, during the past biennium, in addition to 38,640 specimens examined for intestinal parasites, made 5,137 other microscopic examinations, 4,547 of these being water analysis. Pasteur treatment was given to a total of 619 patients without a single death. Under the plan by which the State Board of Health purchased diphtheria antitoxin at the lowest cost, 6,932 packages were distributed. These five items alone amount to an annual saving of $111,723 to the State. The cost of maintaining the Laboratory was an annual appropriation of $2,000 from the legislature, plus approximately $4,000 collected annually as taxes from water companies.”

“Pasteur treatment - A treatment for infection by the rabies virus in which a series of increasingly strong inoculations with attenuated virus is given to stimulate antibody production during the incubation period of the disease.

Read more: www.answers.com/topic/pasteur-treatment#ixzz1WRxbkBXr
Blood Lead Testing: Avoiding Sample Identification Errors

On July 5, 2011, the Blood Lead Laboratory at the NC State Laboratory of Public Health (NCSLPH) began enforcing two long-standing policies regarding sample identification requirements: “specimens must be labeled with the patient’s first and last name and date of birth” and “laboratory testing will not be performed unless the information of the specimen tube exactly matches information on the collection form.”¹ The reason behind enforcement of these policies is not to make life more difficult for clinic staff or patients. Rather it is designed to protect patients from an incorrect diagnosis and treatment (or lack thereof) should their sample be labeled incorrectly. It also protects the submitting clinic and NCSLPH from potential legal action if results are reported on the wrong patient.

If samples are misidentified, it can affect “the patient whose treatment was based on the results, the patient whose sample it actually was who may have gone untreated, and the healthcare workers (including laboratory staff) who were directly involved with the patient or the specimen.”² It is possible that a child who has an elevated lead level is not identified, leading to continual exposure and possible long-term neurological effects. If it is resulted as an elevated level, the family will be subjected unnecessarily to follow-up investigation to identify the source of the lead exposure, and the child will be subjected to additional testing since the established protocol is to “continue testing every 2-3 months until 2 consecutive venous or capillary tests are <10 μg/dL.”¹ A single

![Preferred Labeling Methods](image)

- Legibly Hand Written
- Typed
- HIS Labels are Acceptable

![Requisition Form](image)

- Must Match Tube EXACTLY

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Laboratory / Fall 2011

Blood Lead Testing cont. from page 5

letter can cause a question in patient identification. For example John becomes Joan with the change of a single letter. If a patient has multiple last names, especially common names, specimen identification can also be problematic. John Smith Jones may be written on the requisition form, but a specimen labeled John Smith, John Jones, or John Smith Jones could be three different patients.

According to the Clinical and Laboratory Standards Institute (CLSI), a specimen should be labeled with the patient’s first and last names, secondary patient identifier (NCSLPH uses date of birth), date and time of specimen collection, and initials of the person collecting the specimen. Including a second patient identifier is an additional means to protect a patient from potential incorrect results. It is not only good laboratory practice, but also a requirement of some laboratory regulatory agencies. One of the 2011 National Patient Safety Goals of Joint Commission for Accreditation of Healthcare Organizations (JCAHO) is to “use at least two patient identifiers when providing laboratory services.”

The NCSLPH uses patient first and last name and date of birth as the two patient identifiers.

It is said that “70% of the information a physician uses to diagnose and treat a patient comes from the laboratory.” Errors can occur at any point in the testing process. However, the majority of these errors happen during the pre-analytical phase (collection, labeling, and processing). While it is impossible to completely eliminate errors, identifying patient labeling and requisition errors is one step to reduce the chances of patient harm due to misdiagnosis.

Submitted by: Jennifer Anderson, MPH, MLS(ASCP)CM Supervisor, Blood Lead Laboratory

REFERENCES

How I Spent My Summer Vacation

This summer I spent five weeks in Rwanda, Africa working for the American Society for Microbiology (ASM) teaching basic bacteriology to three mentees at Kanombe Military Hospital. Kanombe is located in the capitol city of Kigali and provides medical services to military personnel and their families. They also serve the immediate community and have goals to become a referral hospital for districts outside Kigali.

My role was to mentor these three laboratorians so that the lab could improve the bacteriology services offered and get started on the path toward accreditation by the WHO-AFRO (World Health Organization, Africa). Some cultures were being performed as well as cell counts and Gram stains. However, the quality of these services was lacking as the technologists possessed only basic skills and knowledge. While they had attended a secondary school for laboratory science, they were all new to Microbiology and did not have the necessary experience needed to provide quality results.

A non-governmental organization (NGO) had recently provided them with refrigerators and incubators, but they had only a Bunsen burner to cook their media and small flasks so that they could only make about ten plates at a time. This severely hindered our capability to have what we needed on hand to culture and identify isolates from the samples we received. We were able to increase this capacity by directing another employee to make media for us daily.

Continued on page 7
Many of the basic reagents or tests used to identify the most common pathogens were not available or, if available, were often outdated. A list of required supplies was created and ordered, but given the difficulties of obtaining many of the items in Africa, they did not arrive while I was in-country. ASM had placed an order for many of the items I would need, but this also did not arrive in time to help me with my teaching.

I had to become very creative not only in how I could get the task completed or determine the identification of the organism, but also in my communication with the mentees. French is the language of Rwanda (as well as Kinyarwanda, their native tongue), and so we had a bit of trouble understanding each other. Though they do speak some English, writing things down often helped improve understanding as well as drawing pictures. In the end, I became quite adept at deciphering what a conversation was about, even if spoken in French or Kinyarwanda.

While at Kanombe, I implemented performing quality control on all procedures and media made, stressed the importance of performing preventive maintenance on all equipment, wrote numerous Standard Operating Procedures (SOPs) and policies, created forms for documenting the new processes I implemented, created a duty roster, took inventory, organized cabinets and work benches, made a presentation to the hospital physicians on antibiotic panel selection, conducted competency assessments on each of the three mentees, wrote a quality improvement plan, and wrote many reports on my progress and accomplishments as required by ASM.

By the time my visit came to an end, I believe I left them with the skills they need to continue on and further their capabilities, as well as having made some special friendships with the laboratory staff. I may be requested to return for a follow-up visit to see that things put in place have been maintained and to provide mentoring again as they continue their work toward the goal of WHO accreditation.

Submitted by:
Cami Hartley, MLS (ASCP) CM
Supervisor, Microbiology Unit
New on CDC websites:

Have you looked at the CDC websites recently? I found some new items that may be helpful to a lot of folks and the information is free!!

At www.cdc.gov/dls/waivedtests, there are some new educational materials that can be downloaded and printed. For waived testing, materials currently available include a poster and booklet for personnel who perform waived testing. The booklet contains a lot of valuable information, resources, and blank forms that can be used in your laboratory.

At www.futurelabmedicine.org (the home page for Best Practices in Laboratory Medicine), there is now a 60 minute on-line tutorial available. “The A-6 Cycle: Review and Evaluation Methods for Quality Improvement” is free and may be taken for continuing education credit. This tutorial may be of interest to those who actively work with quality improvement (QI) projects. Tip: this tutorial is not easy, look at the content on this website first. You must register with the CDC Best Practices web site in order to view the tutorial.

Submitted by:
Karen Sanderson, MT(ASCP)SC
QA Manager, NCSLPH

Now Available Online: Rabies Packaging and Shipping Training

Proper packaging and shipping of rabies specimens results in optimal integrity of the sample, ensures the safety of all staff handling the specimen (submitters, shippers and testers), expedites test results, and ensures compliance with the Department of Transportation (DOT) regulations. Anyone needing guidance or continuing education in submitting rabies specimens to the NCSLPH for testing can view the “Guide to Rabies Packaging and Shipping” presentation on the Rabies Virus page of the SLPH website at http://slph.ncpublichealth.com/virology-serology/rabies.asp. (In addition to the link to the presentation, there is a wealth of rabies testing information on this page.) The link to the training is also available on the SLPH home page http://slph.ncpublichealth.com under “What’s New.”

Previously, a similar presentation was only given at annual conferences for animal control officers. Now that the training is online, it is accessible to everyone who submits rabies specimens for testing, including health departments, private veterinary practices, and animal control. The training contains:

- Pictures of all materials needed;
- Step by step instructions for packaging and shipping;
- Weekend and holiday testing and shipping guidelines;
- Reasons for unsatisfactory test results;
- Explanations for why the rabies test may not be performed;
- “What’s wrong with this picture?” illustrating actual examples of improper shipping; and,

“What’s Wrong with this Picture?” An example of improper shipping of a specimen for rabies testing.

Cont. on page 9
Links to other resources (at the very end after the link to the quiz).

The training may be viewed at one’s own pace either by using the arrows at the bottom of the screen to advance slides or by clicking on the current slide to advance to the next. To receive 1.0 contact hours of continuing education, the quiz at the end of the presentation must be completed and passed. The quiz is administered through QUIA, an online web testing and survey system. Instructions for creating a QUIA account and registering for the rabies class are given on the initial page after clicking on the training link and may be printed for reference. Participants are allowed two attempts to pass the quiz. Once the test has been scored, it is necessary to click “Done” for a certificate to be issued by e-mail. The presentation can also be viewed without taking the quiz for those who have taken it previously or who just want to look through the slides for informational purposes.

The “Guide to Rabies Packaging and Shipping” is a practical tool that will, hopefully, be used by many to better understand the requirements for a properly submitted sample. Pictures such as the one shown below are included as a way to test one’s knowledge and understanding of the material presented. A short survey may be completed at the end of the training to offer any suggestions or feedback. Be sure to check out this new training on your next visit to the SLPH website!

Submitted by:
Laura Fierke
Virology/Serology Unit

Revised Workshop for Preparedness Training for Clinical Laboratories

The Bioterrorism and Emerging Pathogens Unit has provided training to clinical laboratorians in North Carolina since 2003. This hands-on workshop provides practical methods that clinical laboratorians can use to recognize agents of bioterrorism, including Bacillus anthracis, Brucella spp., Burkholderia spp., Francisella tularensis, and Yersinia pestis. As a result of six laboratory exposures to either Brucella spp. or Francisella tularensis in North Carolina sentinel laboratories in 2010 and the need to better be able to identify possible agents of bioterrorism, the workshop was reworked to emphasize laboratory safety, exposure prevention and better organism identification.

Training now begins before the participants arrive at the State Laboratory. Individuals are asked to view a pre-workshop presentation titled, “North Carolina’s Role in Preparedness”. The pre-workshop presentation describes the critical aspects of laboratory preparedness, surveillance and reporting, and the response for bioterrorism. It also explains how clinical laboratories can access state and regional public health laboratories for resources and training about response to bioterrorism and chemical threats. The pre-workshop presentation is presented online and can be viewed by the participants prior to the date of the workshop. An anonymous pre-workshop survey may also be completed. The Bioterrorism Unit periodically studies the effect of their training courses and projects on laboratory practices. Participants are contacted in 3-6 months to see if any changes in laboratory practices were made due to information provided in the course. These tools provide attendees a foundation of which to build upon using the information that will be presented during the workshop.

Safety is one of the most important aspects of working in the laboratory. There is the need to safely recognize that the organism may be present in a culture, perhaps posing a threat to the technologists or those unsuspecting employees/visitors in the laboratory. Safety presentations now included in the morning session include “Staying Safe in the Microbiology Laboratory” and the informative and interactive “Biosafety and Biosecurity.” Biosafety Cabinets are the primary means of containment for working safely in the laboratory. Because they are one of the most important pieces of equipment in the laboratory, a “Biosafety Cabinets” presentation is given to instruct attendees on how to safely and properly work in a Biological Safety Cabinet. The “Agents of Bioterrorism” presentation not only discusses the gram stain, biochemical reactions and colony
morphology of each agent, but exposure prevention and laboratory safety practices are also discussed. Time is allotted during this presentation for open discussion about safe practices and specimen handling. Because safety and exposure control proved to be important topics in 2010, the Bioterrorism Unit responded by including more safety information in the workshop.

There are now three sections of the Laboratory Exercises portion of the workshop: Room 1 – Learn, Compare and Contrast, Room 2 – Test Your Knowledge and Room 3 – Laboratory Safety Inspection. Previously in Room 1, participants of the workshop were only able to view each agent of bioterrorism on plates located inside of a Biological Safety Cabinet without touching them. Attendees are now able to directly compare and contrast agents of bioterrorism with organisms commonly seen in the laboratory. Attenuated strains and those similar to a bioterrorism agent are used to show similarities and differences from those agents that are commonly seen in the microbiology laboratory, i.e. *Bacillus anthracis* vs. *Bacillus cereus* and *Francisella tularensis* vs. *Haemophilus influenzae*. Over 75 completely sealed Sheep Blood agar, Chocolate agar and other media plates are provided for individuals to physically manipulate while in the hands-on portion of the workshop. Biochemical tests, gram stains and color photographs with extensive organism descriptions are provided to aide in the differentiation of the organisms. Due to the increased interactive nature in Room 1, the amount of time spent in this area has been increased to allow participants the opportunity to study the organisms longer and at their own pace. When this section of the laboratory portion has been completed, participants move to Room 2 where their knowledge of the organisms will be tested by what they see in gram stains and by questions asked at different stations set up in the teaching laboratory. In Room 3, participants are asked to perform a safety inspection, noting not only issues with safety, but also other issues such as employee work habits and basic microbiological practices and procedures. In this exercise, the knowledge of biosafety, biosecurity and proper work inside and outside of the Biological Safety Cabinet is tested. All three sections were designed to give the workshop attendee a complete interactive and informative laboratory experience that ultimately aids in the better retention of the information presented.

Terrorism using chemical agents poses a similar threat to the public as a whole. At least a basic knowledge of the agents that may be used and the capabilities of the SLPH Chemical Terrorism Unit should be known. That is why an intriguing and enlightening presentation titled, “Chemical Terrorism” has been included in the day’s agenda. Information is provided about the Chemical Terrorism Unit’s testing capacity and its network participation with hospitals and other first responders within North Carolina. The talk also provides information about those agents that may be used in a chemical attack, such as cyanide, mustard gases, nerve agents and toxic industrial chemicals.

The Preparedness Training for Clinical Laboratories Workshop is offered three times per year at the North Carolina State Laboratory of Public Health. Visit the North Carolina State Laboratory of Public Health’s website at [http://slph.ncpublichealth.com](http://slph.ncpublichealth.com) and click the Laboratory Improvement tab to view a list of dates and times for future workshops.

Submitted by:
LaVonda Benbow BS, MLT(ASCP) CM
Lab Improvement Consultant/BT Training Coordinator
October 26, 2011 Web Conference
Newborn Screening: an Update
NCLTN
(North Carolina Laboratory Training Network)
This program will be presented in Adobe Connect format.

WEB CONFERENCE DESCRIPTION: North Carolina initiated its Newborn Screening program in 1966 with a screening test for Phenylketonuria (PKU). Almost fifty years later the program has grown to include tests for more than thirty disorders that may cause mental retardation or premature death.

This educational web conference will highlight the Newborn Screening Program. Topics included will be laboratory testing, reporting protocols, follow-up processes and treatments for affected newborns. New testing involving molecular techniques for Cystic Fibrosis will be highlighted. Additionally, advances in Newborn Screening disorders and the new State Laboratory of Public Health facility will be discussed.

OBJECTIVES: At the conclusion of this web conference participants should be able to:

1. Demonstrate the steps of proper heel stick collection
2. Identify the criteria for satisfactory specimens, both in specimen quality and documentation (use of the Hearing Link Program)
3. Discuss existing tests for disorders, especially molecular testing procedures for Cystic Fibrosis
4. Specify requirements for follow-up testing so that acceptable specimens are collected and submitted in a timely manner
5. Communicate means of result reporting: hard copies, online
6. Describe the future of Newborn Screening in North Carolina

DATE AND TIME: October 26, 2011, 1:00 pm to 4:00 pm.
Please be sure to log in 5-10 minutes prior to this time.

REGISTRATION DEADLINE: October 21, 2011

HOW TO REGISTER: Each applicant must complete the online registration form which can be found at:
http://www.quia.com/sv/535433.html. An e-mail letter will be sent to each individual confirming registration.

If you have never attended a Connect Pro meeting before please test your connection:

Get a quick overview:
http://adobe/com/goconnectpro_overview

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AGENDA

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<td>Questions/Training/Evaluation/Continuing Education/Adjourn</td>
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WHO SHOULD ATTEND:
Those in healthcare facilities who interact with the Newborn Screening program in any manner, including form submission, collection, and follow-up and care for newborns. Those with collection responsibilities are especially encouraged to register.

CONTINUING EDUCATION: 3.0 P.A.C.E Approved Contact Hours will be awarded.

FEE: There is NO FEE for this program.

FOR ADDITIONAL INFORMATION:
Contact Ann Grush, Newborn Screening, 919-807-8881 or e-mail at ann.grush@dhhs.nc.gov
Who’s Who in Laboratory Improvement

The Laboratory Improvement Unit at the North Carolina State Laboratory of Public Health (SLPH) is well known for the training and consultative activities provided to laboratory professionals across the state. The unit has seen numerous personnel changes over the last couple of years and would like to take this opportunity to introduce readers to current staff members.

The group is headed by Patty Atwood, Laboratory Improvement Coordinator. Patty joined the unit in April of 2010 after working for the previous six years as supervisor of the Hemoglobinopathy and Cystic Fibrosis Labs in the Newborn Screening Unit at SLPH. She received her Medical Technology degree from Western Carolina University and is certified by the American Society of Clinical Pathology (ASCP). Patty began her career as a hospital generalist and later worked as a Blood Bank Technologist at Rex Hospital. She began working at SLPH in 1980 and left in 1991 to work part-time at Kaiser Permanente while raising a family. In 2002, she returned to SLPH and is now proud to be a part of Laboratory Improvement. Patty handles the administrative and managerial tasks of the unit and helps to coordinate daily activities.

Michelle Rufus serves as Administrative Assistant for Laboratory Improvement, joining the group in September of 2009 from another state agency. Michelle has been dubbed the “Voice of Lab Improvement” since she is in contact with all of the students that attend the various workshops hosted by the group! She processes registrations and fees, compiles workshop manuals, sends out confirmations and certificates, and greets and escorts participants to the classroom areas. In addition, Michelle is responsible for ordering supplies for the unit, compiling numerous monthly reports and logs, grading and issuing certificates for the online Urine Microscopic Examination, and teaching phone training to new SLPH employees.

There are three consultants in the Raleigh office of Laboratory Improvement. Their primary responsibility is to identify, develop and present training opportunities for laboratory personnel throughout the state. Kristy Breedlove has been with the group since 2002 and has been present for many of the transitions the unit has undergone. Kristy is a graduate of North Carolina State University with a degree in Biology and a minor in Genetics. She has received advanced safety certificates from the National Safety Council and works with local health departments on issues relating to laboratory safety. Kristy teaches Microscopy, Wet Mount and Waived Testing workshops and directs Environmental workshops. She also oversees the Competency Assessment Program that is provided to local health departments. Kristy enjoys computers and technology and will manage the new Adobe Connect web conferencing system, as well as implement any needed web updates to ensure accurate information is provided to clients.

Tiffany Perdue joined Laboratory Improvement as the STD/HIV Consultant in June 2010. She received her Clinical Laboratory Science degree from East Carolina University and is ASCP certified. She has worked as a generalist at Duke Raleigh Hospital and as laboratory supervisor for a urology practice. Tiffany teaches workshops for Laboratory Methods in the Diagnosis of Gonorrhea, Basic Urinalysis and Syphilis Serology. She also manages the microbiological media contract which provides selective culture media to local health departments for the identification of Neisseria Gonorrhea. Tiffany recently presented a web conference entitled “An Overview of Gram Staining” and plans to develop additional web conferences and online trainings in the coming year.
Michaela Harvey-Creech is the third consultant in the Raleigh office and the newest member of Laboratory Improvement, joining the group in June 2011. Michaela holds a degree in Laboratory Animal Science from NC A&T State University and a Medical Technology degree from Saint Augustine’s College. She has worked at Lab Corp and Solstas Laboratories and taught high school science courses in the Guilford County School System for four years. Once her training is completed, Michaela will be teaching various workshops, beginning with Microscopy and Wet Mount. She also plans to develop a Basic Microbiology and Gram Staining workshop for early 2013.

Diana Scarborough serves as Laboratory Manager for the unit, overseeing the equipment and supplies in the laboratory area. Diana has a degree in Medical Laboratory Technology and worked extensively as a Blood Bank Technologist at Wake Medical Center in Raleigh. She joined SLPH in 2003 as a technologist in Newborn Screening and moved to Laboratory Improvement in December 2009. Diana is responsible for setting up the laboratory exercises for workshops and provides assistance to students during the exercises. She also assists with the Competency Assessment Program, organizes product evaluations, oversees quality assurance activities in the unit’s laboratory area, and is the person to contact when requesting stock cultures used in quality control activities.

Janice West joined the unit in 2006 as a Laboratory Technologist. Janice attended UNC-Wilmington and received a degree in Marine Biology with a minor in Education. She has previously worked as a Vocational Evaluator with Dorothea Dix Hospital and as a teacher in the Wake County School System. Janice performs quality control on the STD media and sends out acceptable lots to local health departments. She works closely with the Laboratory Manager to set up workshop exercises and assist students. Janice also presents an overview of SLPH to new employees and provides CE opportunities for all employees by setting up the viewing of teleconferences and other programs. Recordings of these presentations are kept in a lending library, which Janice makes available to laboratorians across the state.

In addition to the Raleigh staff members, Laboratory Improvement has four other employees who work hard to directly serve local health departments. These regional consultants provide consultations, assessments and trainings to over 40 health department laboratories who participate in the state Clinical Laboratory Improvement Amendment (CLIA) Contract Program. Technical assistance is provided in all areas of laboratory management, to include technical procedures, administrative policies, quality assurance, personnel educational requirements, accreditation and laboratory facility design. Guidance and recommendations are also provided to all other counties on an as-needed basis. The four regional consultants work closely with Raleigh staff to ensure that trainings and educational opportunities meet the needs of local laboratorians.

Sherri Felts joined Laboratory Improvement in 2005 as a Regional Consultant for the eastern area of the state and is based in Greenville. Sherri received a Medical Technology degree from the University of Kentucky and is certified by ASCP in Medical Technology and Blood Banking. She has previously worked at Pitt County Memorial Hospital and East Carolina University as a Senior Medical Technologist and Adjunct Clinical Instructor.

Tracey Shives became Regional Consultant for the Winston Salem area in early 2008. Tracey received a degree in Biology and later in Clinical Laboratory Science from UNC-Chapel Hill. She is ASCP certified and has previously worked as a technologist in various hospital laboratory settings. Before joining SLPH, Tracey worked for 10 years at Rowan Regional Medical Center, supervising the Microbiology Department for five of those years.

In October of 2010, Karen Wall joined the unit as Regional Consultant for the south central area of the state. Karen attended East Carolina University where she received a degree in Clinical Laboratory Science and is ASCP certified. She has experience working as a Medical Technologist at several different hospitals in the state and has served as a consultant for physician office laboratories. Before joining Laboratory Improvement, Karen was Laboratory Supervisor at Wilson County Health Department.

April Hill began work in April of this year to serve as Regional Consultant for the western part of North Carolina. April
received her Medical Laboratory Technology degree from Henderson Community College in Henderson, Kentucky and her Clinical Laboratory Science degree from Thomas Edison State University in Trenton, New Jersey. April is certified by ASCP and by American Medical Technologists (AMT). April has worked extensively as a generalist in the clinical laboratory and most recently served as Technical Specialist for Ancillary Testing and Pre-Analytical Services at Bay Pines VA Medical Center in Bay Pines, Florida.

Laboratory Improvement strives to improve public health by encouraging and promoting good laboratory practice. To fulfill this mission, the unit seeks to provide current and accurate information relevant to all areas of clinical and environmental laboratories. Workshops are offered throughout the year in Raleigh and occasionally in other areas of the state as travel permits. Earlier this year, Laboratory Improvement began using Adobe Connect for web conferencing so that continuing education credits can be obtained when travel restrictions limit attendance at live events. Recorded teleconferences on a variety of topics are available, and may be checked out through the unit’s Audio Visual (AV) Library. Online self-studies in Urine Microscopics, Newborn Screening Form Training, and Rabies Packaging and Shipping are found on the NCSLPH website, with additional self-studies planned for the near future.

For a workshop booklet and list of course descriptions, go to http://slph.ncpublichealth.com/doc/Laboratory_Improvement_Workshops_2011.pdf. Workshop applications may be found at http://slph.ncpublichealth.com/doc/WorkshopApplication.pdf. For more on Laboratory Improvement and available resources, visit the SLPH website at http://slph.ncpublichealth.com and click on the “Lab Improvement” tab on the right. To reach a Laboratory Improvement staff member, call 919-733-7186.

Submitted by:
Patty Atwood, MT (ASCP)
Laboratory Improvement Coordinator
As a former CLIA surveyor, one of my pet peeves was when I surveyed a laboratory and found that either they
did not have a product (package) insert for their test kit, or that the one in the procedure manual was 10 years
old.

The CLIA regulations for waived testing state “follow manufacturers’ instructions for performing the test”
(42 CFR §493.15(e) (1).  If you don’t have the instructions available, how can you follow them? Some labs pull
out the quick instruction card that is in the test kit and post it on the bulletin board, but this card does not
include all of the essential information found in the product insert.

For non-waived testing, the CLIA regulations state at 42 CFR §493.1252(a) “Test systems must be selected by
the laboratory. The testing must be performed following the manufacturer’s instructions....”

If you do not use the manufacturer’s testing information or product insert as part of your procedure or you
don’t keep a copy in your procedure manual, then file the product insert in a place where you can easily refer
to it as needed. When you receive a new lot number of test kits, check the product insert to see if it has been
updated. Usually there will be a notice on the front, and some manufacturers highlight the changed infor-
mation. The version date of the insert is usually printed on either the first or last page. If the version has
changed, review the insert to see if any changes affect your test procedure and if so, incorporate these chang-
es and inform all testing personnel as well as your lab director. Don’t forget to replace the product insert you
have on file as a reference. Keep the retired inserts for a minimum of two years after they have been replaced
or retired.

Read the instructions carefully. The language used to convey the instructions is important. Words like
“always”, “must”, “shall” and “required” mean the language is regulatory and MUST be performed. Words
like “should” or “recommend” mean the actions are not regulatory for waived test procedures, but it is good
laboratory practice to perform these actions.

Table 7. Components of the Manufacturer’s Product Insert from page 12 of MMWR Good Laboratory
Practices for Waived Testing Sites, (November 11, 2005), lists the components usually found in a product/
package insert and a description of the information provided in each section. Listed below are some
highlights from this table and some tips I hope will be helpful.

Intended Use: This section describes the test purpose. It may address whether it is used for diagnosis or as a
screening test for a target population. It also describes whether it is for professional use or self-testing. Tip:
If you use a test approved for self-testing (i.e. home pregnancy test) in a patient testing setting (e.g. physician
office laboratory), then you are modifying the FDA approval and the test becomes high complexity.

Storage/Stability: This section specifies the conditions for storing reagents to protect their stability. There
may be different expiration dates when stored at different temperatures. For example, a kit may be stable for
one year when stored in the refrigerator, but only 3 months when stored at room temperature. Tip: About
three years ago, a manufacturer changed storage conditions of a popular control product from < -10°C
to < -15°C and this temperature change caught many people unawares when it was found during their
laboratory inspection.
Specimen Collection and Preparation: This information details requirements for specimen collection, handling, storage, acceptability, etc. Some manufacturers have different expiration dates for specimens stored refrigerated vs. frozen. Tip: Be aware of the allowed time between collection and testing, and the centrifuge speed and times required for specimen preparation. Adherence to these pre-analytical steps is important to have a good quality specimen for testing.

Test Procedure: This section provides step-by-step instructions for performing the test. Tip: If the laboratory decides to modify any of these steps, then the test becomes high complexity and a full validation of the change is required.

Interpretation of Results: This section describes how to read and interpret the test results. Follow instructions to use the correct units of measure, recognize invalid tests, and when and if a confirmatory test is required. Tip: Test results must be reported in the same manner as described in the package insert.

Limitations: This section gives valuable information about conditions that may influence the test results or for which the test was not designed. It describes possible interferences and may have a warning that the test is not approved for use with alternate specimen types, etc. Tip: A few years ago, a popular waived test kit for mononucleosis included a statement to not use the test on children younger than 16 as it had not been tested on children. This statement caused many pediatric and family medicine practices to change to another product.

Expected Values: Always report the test result as designed in the package insert. If the test is qualitative (positive/negative), it must be reported this way. Tip: If the package insert states that the laboratory must determine their own reference range, then the laboratory must have documentation to support the expected range they are reporting, even if they are using the one from the manufacturer.

In summary, the manufacturer’s product insert is a valuable piece of information to use and have as a reference. Not only does this information apply to test kits, but also to quality control, calibrator, and reagent inserts. Your laboratory inspector or CLIA surveyor will use these inserts and manufacturer’s manuals as a reference to verify that your testing is being performed correctly, so don’t let yourself be caught by surprise on a lab inspection. Know what is in these documents!

Submitted by:
Karen Sanderson, MT(ASCP)SC
QA Manager, NCSLPH
Tech Talk

Question 1. Where can you get Stock Cultures?

Stock cultures are available free of charge at the North Carolina State Laboratory of Public Health. They may be requested by accessing the Stock Culture Order Form at: [http://slph.ncpublichealth.com/Forms/StockCultureOrderForm.pdf](http://slph.ncpublichealth.com/Forms/StockCultureOrderForm.pdf)

The most commonly requested organisms are as follows:

<table>
<thead>
<tr>
<th>Test</th>
<th>Recommended QC Organisms</th>
<th>Expected Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gram Stain</td>
<td><em>Escherichia coli</em> ATCC 25922</td>
<td>Gram Negative Rods</td>
</tr>
<tr>
<td></td>
<td><em>Staphylococcus aureus</em> ATCC 25923</td>
<td>Gram Positive Cocci</td>
</tr>
<tr>
<td>Oxidase</td>
<td><em>Pseudomonas aeruginosa</em> ATCC 27853</td>
<td>Oxidase Positive</td>
</tr>
<tr>
<td></td>
<td><em>Escherichia coli</em> ATCC 25922</td>
<td>Oxidase Negative</td>
</tr>
<tr>
<td>Colisure® or Colilert®</td>
<td><em>Pseudomonas aeruginosa</em> ATCC 27853 or ATCC 10145</td>
<td>Negative for both total coliforms and fecal coliforms</td>
</tr>
<tr>
<td></td>
<td><em>Klebsiella pneumoniae</em> ATCC 31488</td>
<td>Positive for total coliforms and negative for fecal coliforms</td>
</tr>
<tr>
<td></td>
<td><em>Escherichia coli</em> ATCC 25922 or ATCC 11775</td>
<td>Positive for both total coliforms and fecal coliforms</td>
</tr>
</tbody>
</table>

Note: Always check product insert for specific Quality Control organisms.

Question 2. Some local health department GC culture procedures contain the statement, “Dispose of all cultures by decontaminating with full strength Clorox for 15 minutes. Double bag and discard in trash can.” Is this an acceptable practice?

Yes, this is considered a regulated waste by OSHA (29 CFR 1910.1030) and by NC Statute 15A NCAC 18A.1200. Letting the plates sit in full strength Clorox for 15 minutes is a form of chemical waste “treatment” which renders the GC organism non-infectious. There is no blood associated with the plate, but there can be other potentially infectious material (OPIM) such as vaginal secretions or material from a male culture.

According to 15A NCAC18A.1203 General Requirements for Regulated Medical Waste paragraph (a): Regulated medical waste shall be treated prior to disposal. Acceptable methods of treatment are as follows: (2) microbiological waste – incineration, steam sterilization, microwave treatment, or chemical treatment.

Because most health departments do not have autoclaves, this is a cheap and simple way to treat their regulated waste.

Submitted by:
Diana Scarborough, Laboratory Improvement
Kristy Osterhout, SLPH Safety Officer
The NCSLPH continues to recognize exemplary employees by awarding the State Lab Employee of the Quarter. Employees are encouraged to nominate co-workers who demonstrate outstanding work ethics and always lend a helping hand.

The Spring Quarter recipient was Laura Fierke from the Virology/Serology Unit. Laura volunteered to serve as the coordinator of SLPH Wellness Committee and has done an outstanding job leading this effort. She has worked tirelessly during the day and after hours to organize initiatives such as Red Shirt Day, Take the Stairs, the Walking Challenge (70 participants from the lab!), Friday Line Dancing, and a variety of wellness classes. Laura keeps employees informed through posters and e-mails about wellness opportunities available at the State Laboratory and around town. She has demonstrated unflagging energy and enthusiasm for this role that is reflected in her own commitment to health and physical activity as a participant in running marathons and planning for a triathlon.

Laura has accomplished all this through great teamwork while maintaining excellent performance in her demanding role as “floater” for the Virology/Serology Unit. Her efforts promote physical activity, good health and well-being for all employees choosing to participate, either at free or affordable cost, which is a great morale booster in these difficult times.

Thank you, Laura, for all that you have done to improve our well-being!

The Summer Employee of the Quarter was Kathy Benson from the Microbiology Unit. Kathy is always willing to learn new things and to help her work group when and where she is needed. During the recent medical leave of a co-worker, Kathy managed two laboratory areas for three months with minimal assistance. She is a great team player, and her expertise and willingness to assist her co-workers is a crucial asset for continuity of operations in the Microbiology Unit, especially during periods of personnel shortages. Since many areas in Microbiology are one person laboratories, it is valuable to have a staff member as experienced as Kathy to help fill the gaps. She is also serving as a member of the Central Accessioning Team for the new laboratory facility and contributes to the overall success of the SLPH.

In addition to Kathy’s technical abilities, she always has a smile on her face and a great listening ear. Her positive attitude and pleasant disposition lift the morale within her work group. She is a kind and caring person who loves to read and do crossword puzzles. Finally, Kathy is a long time blood donor who has earned her “5 Gallon” pin from the Red Cross.

Thank you, Kathy, for all your contributions to the State Laboratory of Public Health!

**Special Kudos!**

A special Kudos goes out to Germaine Buchanan. Germaine is the receptionist for the State Laboratory. She’s the first person you see when you enter the building, and her voice is the first you hear when you call the main number. Germaine is not only the receptionist, but helps to maintain security of the building by making sure all visitors and staff are properly signed in and identified. She is also remarkable at multi-tasking and is able to bring quick order to the occasional, spontaneous moments of chaos that can easily happen whenever lots of people come and go. Kudos to Germaine! She juggles lots of balls at the same time and rarely, if ever, drops one.
We are happy to welcome the following new employees to the State Laboratory:

- Sherrissa Becton – Newborn Screening
- Sharmila Bose – Virology
- Daryn “Cole” Watson – Virology
- Cordelia Williams – Virology
- Michaela Harvey-Creech – Laboratory Improvement
- Louise Pratt-Whitted – Microbiology
- Wendy Johnson – Newborn Screening
- Michele Andrews – Environmental Sciences

We wish to thank the following employees for their years of service preceding recent separations or retirements:

- 4/18/11 – Katja Manninen – Molecular
- 6/30/11 - Lucy Burke – Newborn (Ret.)
- 6/30/11 - Shirley Jordan – Operations (Ret.)
- 7/31/11 – Scott Hansen – Newborn (Ret.)
- 8/12/11 – Shawanda Long – Cytology
- 8/16/11 – Monique Venable – Cytology
- 9/31/11 – Michael Merryfield – Cytology (Ret.)

Congratulations to Justin Blake of the Mailroom on his recent promotion!

If you would like to recognize a co-worker at your facility or introduce a new employee, please contact Janice West at (919)733-7186 or janice.west@dhhs.nc.gov.
The Safety Corner
Laboratory Safety’s “Top 10” List:
Opportunities for a Safer Workplace

In the next issue of Lab-Oratory, the Safety Corner will begin outlining the top 10 safety violations found in the laboratory. Many times safety hazards go unnoticed until either an OSHA inspector issues a citation or even worse, someone gets hurt. In 2007-2008, the NCSLPH Laboratory Improvement section performed mock OSHA inspections on forty local health department laboratories. In general, we found most laboratorians were very safety conscious and really wanted to provide a safe environment for themselves and their co-workers. However, we started noticing trends and realized many of the laboratories had the same safety concerns. After the reports were compiled, results were compared and the top 10 most cited violations were found.

What were the top violations we found? Here’s the Top 10!

1. Safety shower/eyewash
2. Biohazard warning signs
3. Fire extinguisher
4. Various signage
5. Environment issues
6. MSDS and chemical inventory
7. Equipment and electrical concerns
8. Mercury spill kits
9. Emergency phone numbers
10. Personal protective equipment

Keep in mind these categories are broad and encompass various deficiencies. Each quarter, the Safety Corner will explore one category and go over the specific details. Hopefully at the end of the series, your laboratory will be OSHA compliant with a safe work environment for you and your co-workers!

If you have any questions regarding safety, please contact Kristy Breedlove at kristy.breedlove@dhhs.nc.gov or (919) 733-7186. Look for the next installment of The Safety Corner when we will continue with the series, “Laboratory Safety’s “Top 10” List: Opportunities for a Safer Workplace”!

Submitted by:
Kristy Breedlove, BS, Laboratory Improvement Consultant, NCSLPH

Patty Atwood, Editor
Lab Improvement
La’Vonda Benbow, Bioterrorism and Emerging Pathogens
Vacant, Cytology
Michele Andrews, Environmental Sciences
Kristy Osterhout, Administration/Safety Officer

Jennifer Anderson, NBS/CC
Kristy Breedlove, Lab Improvement
Janice West, Lab Improvement
Laura Fierke, Virology/Serology
Kathy Benson, Microbiology
Savitri Mullapudi, Molecular