

Multi-site CLIA Certificate Programs

Laboratory Practices for Limited Public Health Testing

Association of Public Health Laboratories

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Billions of clinical laboratory tests are performed each year in the United States for general health assessment or the prevention, diagnosis or treatment of human illness.^{1,2} These tests are critically important for clinical decision making, including the detection and treatment of infectious diseases. They have a profound effect on both individual and public health.^{3,4}

The Clinical Laboratory Improvement Amendments of 1988 (CLIA) were passed into law to help assure the accuracy of these tests, many of which are performed by personnel with no formal laboratory training. However, CLIA oversight is not always sufficient to guarantee quality testing in the approximately 200,000 clinical testing facilities. Thus, in conjunction with CLIA, integrated systems of clinical and public health laboratories have long been recognized and promoted as a means to support high-quality laboratory practices throughout states and to improve disease surveillance nationwide.

The appearance of new threats to public health in recent years—including emerging infectious diseases and biological terrorism—underscores the need for such integration between clinical testing sites and public health reference laboratories. Indeed, these threats have prompted renewed calls for a national laboratory system with crucial leadership roles for state public health laboratories (PHLs).^{5,6}

Tool for Integration of Lab Systems

One perhaps under-utilized tool to achieve integrated laboratory systems within the public and not-for-profit sectors is the CLIA multiple-site certificate. When the CLIA program was first instituted, this

regulatory option was championed by the late Dr. Carl Blank, former director of the Wyoming PHL and a former CDC official, to preserve and facilitate local public health testing. It allows multiple “not-for-profit or federal, state or local government laboratories that engage in limited public health testing (not more than a combination of 15 moderately complex or waived tests per certificate)” to file a single CLIA application. See Table 1 for details.⁷

Though it presents some supervisory challenges, state PHLs have used the CLIA multi-site certificate from the time the CLIA program was established. In 1994, 12 state PHLs provided support for limited public health testing (LPHT) laboratories and at least three of these state programs were in existence before CLIA was implemented.⁸ Currently, at least nine state PHLs hold multi-site certificates, covering anywhere from one to more than 300 local testing sites.

While inclusion in the multi-site certificate is voluntary for autonomous facilities, it offers important administrative and financial benefits.

Depending on the number of sites on the certificate, there can be significant cost-savings, since only one application fee—based on aggregate test volume—must be submitted to the Centers for Medicare and Medicaid Services (CMS) instead of separate fees for each site. (The CLIA certificate fee schedule is posted at http://www.cms.hhs.gov/CLIA/11_CLIA_Certificate_Fee_Schedule.asp.)

The required inspection fee is based on the total test volume and specialties of all sites. Only one site must enroll in proficiency testing.



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Table 1. CLIA Certificate Types

Final CLIA regulations published in February 1992 allow for three main types of CLIA certificates.

- 1. Certificate of waiver (CW):** Permits facilities to perform only designated *waived* tests; that is, “simple tests with an insignificant risk of an erroneous result” that are exempted from routine CLIA oversight requirements.⁹
- 2. Certificate for provider-performed microscopy procedures (PPMP):** Permits waived testing, as well as microscopic examinations of certain patient specimens by a physician, mid-level practitioner or dentist. (PPMPs are a subcategory of moderate complexity testing and include wet mounts, all potassium hydroxide preparations, urinalysis and other procedures. A complete list is posted at <http://www.cms.hhs.gov/CLIA/downloads/ppmp.list.pdf>.)
- 3. Certificate of Compliance and Certificate of Accreditation*:** Allow a laboratory to perform the full range of clinical testing defined by CLIA, including moderate complexity and high complexity testing. Laboratories holding a certificate of accreditation instead of a certificate of compliance must be accredited by an approved accreditation organization.
- 4. CLIA’s “multi-site exception”** allows multiple public or not-for-profit-entities to submit a single application to secure a CW, PPMP or Certificate of Compliance multi-site certificate for “limited public health testing,” i.e., not more than a combination of 15 moderately complex and/or waived tests per certificate. Each certificate may have its own mix of tests.

* In addition, a certificate of registration enables an entity to perform moderate or high complexity testing for a limited period while it is preparing for a federal laboratory survey or seeking appropriate accreditation.

Source: CMS. Form CMS-116 (07/05) at <http://www.cms.hhs.gov/cmsforms/downloads/cms116.pdf>

In addition, individual certificate sites gain the benefit of technically qualified training and direction to help them maintain CLIA compliance. This is an important asset for laboratories performing moderate complexity testing, which is subject to more stringent requirements than waived testing. In fact, multi-site oversight arrangements can put moderate complexity tests within the reach of public health programs—such as STD and HIV programs—that might not otherwise have the capability to offer them.

APHL-convened Focus Group

In light of growing interest in laboratory networks and partnerships, APHL, with support from a CDC

cooperative agreement, convened a two-day focus group in March 2007 to explore practices associated with successful multi-site, LPHT programs. The meeting was held at the North Carolina State Laboratory of Public Health in Raleigh and included senior staff from seven of the nine state PHLs determined to have a CLIA LPHT multi-site program based on responses to an APHL survey. The group was led by Leslie Wolf, PhD, laboratory director, North Carolina State Laboratory of Public Health. Participants represented the state PHLs in Connecticut, Delaware, Kentucky, Louisiana, Michigan, North Carolina and Tennessee. Staff from CDC's Division of Laboratory Systems also attended as advisors.

Recommended Laboratory Practices for LPHT Multi-site Programs

The specific characteristics and organization of each multi-site program—for example, whether one or more certificates are obtained—will depend upon factors such as the state’s geography, the number of testing sites, test volume and complexity and the standards imposed for waived versus moderate complexity testing. The highest volume tests among those programs represented at the focus group are urine dipstick, urinalysis, hemoglobin, glucose, urine pregnancy, wet mounts, rapid HIV (DE and CT), microscopy (LA) and cholesterol/triglycerides (MI).

Regardless of the organizational configuration, all programs must comply with CLIA regulations that require the designation of specific personnel on the multi-site certificate. Depending on the CLIA certification type, designated personnel include laboratory director, technical consultant, clinical consultant and testing personnel. (See Table 2 for description of Certificate of Compliance personnel). They must also adhere to laboratory standards for personnel, quality assurance (QA), quality control (QC) and patient test management. Programs with sites performing moderate complexity testing must arrange for at least one such site to participate in required proficiency testing and are subject to biennial CLIA inspection.

Table 2. CLIA-mandated Personnel for LPHT Multi-site Certificate of Compliance Programs

CLIA regulations define four categories of personnel who must be named on each multi-site certificate for limited public health testing.

Laboratory Director: Is ultimately responsible for the operation and administration of the program and is often the state PHL director.

Technical Consultant: Reports to the laboratory director (at least in the context of the multi-site program) and is responsible for routine technical and scientific oversight, including enrollment in an appropriate proficiency testing program (for sites performing moderate complexity testing), establishment of a quality control program, staff training and competency assessment and related duties.

Clinical Consultant: Is generally retained by individual sites and must be available to provide consultation regarding the appropriateness of the test(s) ordered and interpretation of test results at each laboratory performing moderate complexity testing.

Testing Personnel: On-site personnel, often nurses, who may perform only those tests authorized by the laboratory director or designee. Testing personnel are responsible for specimen processing, test performance and reporting test results.

Source: 42 Code of Federal Regulations §493.1407, §493.1413, §493.1419, §493.1425.

The recommended practices listed in this report address the basic requirements and go beyond them. They are based on the collective experience of the multi-site programs represented at the APHL focus group.

Table 3. Recommended Good Laboratory Practices for LPHT Multi-site Programs

- #1: Be prepared to use state funds to support the multi-site program.
- #2: Decide at the outset the level of oversight desired for sites performing moderate complexity testing versus sites performing only waived testing, if any.
- #3: Choose technical consultants with appropriate qualifications.
- #4: Assure an appropriate ratio of technical consultants to testing sites.
- #5: Designate a qualified lead staff person at each local testing site.
- #6: Consider the use of a contract to enforce accountability among local sites.
- #7: Consider the use of a policy manual that delineates the responsibilities of the certificate holder and the local testing sites.
- #8: Assure that local sites understand the group consequences of persistent performance deficiencies.
- #9: Explore various means to communicate with local testing sites remotely, but assure some face-to-face contact.
- #10: Develop a procedure manual and standard forms to facilitate proper QA/QC practices.
- #11: Consider the advantages of using uniform methods across sites and bulk buying.
- #12: Develop a user-friendly quality assurance plan and support it with appropriate forms and oversight.
- #13: Arrange for regular training classes at the PHL and/or at local sites.
- #14: Conduct proficiency testing at least annually.
- #15: Assure competency assessment at least annually.
- #16: Conduct internal audits of local test sites at least annually.
- #17: Be on-site for formal CLIA inspections.

#1: Be prepared to use state funds to support the multi-site program.

At a minimum, the cost of a CLIA multi-site program includes certificate and inspection fees, proficiency testing and staff time and travel costs.

Ideally, multi-site certificates should be viewed as program management tools, with *most or all* of these costs absorbed by the certificate holder and/or allied public health programs, such as state HIV and STD programs. In practice, however, local sites—and especially autonomous sites—are sometimes asked to contribute towards the cost of the CLIA certificate and/or proficiency tests.

In Kentucky, for example, the state PHL pays the certificate fee and contributes staff time (between 1.0 and 1.5 full time equivalent), but sites needing proficiency testing purchase their own.

The North Carolina regional multi-site program currently charges sites about \$250/year to cover the costs of CLIA certification and inspection fees and enrollment in an approved proficiency testing program. The state PHL, however, amassed considerable goodwill by purchasing new computers and printers—designated for laboratory use—for all certificate sites. The equipment was purchased with grant money and helped to assure that all sites had e-mail and Internet access.

A few state PHLs have partnered with state health programs to help support the multi-site testing program, based on the rationale that the PHL is helping to assure quality of care and access to tests of public health importance. The Delaware Public Health Laboratory employs a quality assurance officer who is funded in part by the state HIV program and who conducts all HIV training at all sites on the state CLIA certificate. Similarly, the Tennessee Laboratory Services charges all training supplies used for the multi-site program to the nursing division within the state health agency. (Local sites pay for proficiency testing and for travel to state training programs.)

The Michigan Public Health Laboratory has gone

one step further by using its regional CLIA multi-site program (with six multi-site certificates) to establish statewide surveillance capacity for foodborne and infectious disease agents, including bioterrorism (BT) agents. The program was once supported by Epidemiology and Laboratory Capacity grant funds, but as this funding diminished, was switched to BT grant funding. Since federal BT funds are also diminishing, the PHL is exploring the possibility of using general state funds and/or charging local sites a user fee.

#2: Decide at the outset the level of oversight desired for sites performing moderate complexity testing versus sites performing only waived testing, if any.

This decision will be influenced by PHL resources, including the funding and the personnel time available to commit to the program. Some states have opted to impose uniform standards across all sites (including requirements for proficiency testing), while others impose less stringent standards on sites performing only waived testing. In some states, however, the multi-site program is only available to sites that perform at least some moderate complexity testing.

#3: Choose technical consultants with appropriate qualifications.

The technical consultant serves as the PHL's chief liaison and point-of-contact with the testing sites named on the certificate. This position is key to a successful program. The person who holds it should:

- Be, at minimum, a medical technologist or equivalent.
- Have a strong knowledge of quality assurance (QA), particularly as it relates to moderate complexity testing.
- Have practical, multi-specialty clinical experience and expertise (e.g., microscopy, hemoglobin analysis, etc.).
- Have diplomatic skills appropriate for someone who will be representing the state PHL off-site.

- Be compensated at a level commensurate with others who have comparable credentials and supervisory responsibilities.

#4: Assure an appropriate ratio of technical consultants to testing sites.

The precise ratio of technical consultants to testing sites will vary among states. Programs with few testing sites and those located in close proximity to the PHL, or with several sites performing only waived testing, may need only one multi-site certificate and thus one technical consultant. Conversely, programs with many sites, highly dispersed sites and/or sites performing a high volume of moderate complexity testing, may be better served by multiple certificates and thus multiple technical consultants.

In Connecticut, a smaller state with an area of barely more than 5,000 square miles, oversight of 17 testing locations (performing about 14,000 tests/year) is the responsibility of one technical consultant; the Public Health Quality Assurance Manager also oversees the Connecticut Division of Laboratory's QA and safety programs. While the duties associated with the multi-site program are significant, the state does not enforce the same stringent quality standards for its 13 waived sites as it does for its four sites doing moderate complexity testing, thus somewhat simplifying the task.

Some of the larger multi-site program states have devised more complex management solutions. The North Carolina State Laboratory of Public Health has divided its 100 counties—covering 54,000 square miles—into four regions. Participating local health department laboratories in each region are covered by a separate multi-site certificate and served by a separate regional technical consultant. Altogether, the state's 47 participating counties process more than 360,000 tests/year.

This regional arrangement offers several advantages. First, each technical consultant has a manageable "caseload" of testing sites. Second, since the

technical consultants work chiefly out of regional offices, they have more convenient access to the sites they oversee. And third, the consultants are able to collaborate on training activities, to proactively address problems that have arisen in one only region and to copy best practices from one another.

A similar system is used by the Michigan Department of Community Health Laboratory (MDCHL), which oversees 103 local testing sites spread out over almost 100,000 square miles. Through contractual agreement, the state is divided into six health regions, each with its own waived/moderate complexity certificate of compliance. The designated laboratory directors on the certificates are all state PHL employees with the credentials to manage a high complexity facility.

The state's technical consultants, however, are not MDCHL employees. The state provides funding to a high complexity laboratory in each region (and some regions have only one) in exchange for the services of the laboratory manager as the technical consultant for the regional multi-site certificate.

#5: Designate a qualified lead staff person at each local testing site.

Virtually all local sites participating in multi-site certificate programs—at least in the focus group states—are autonomous entities with no direct line of authority to the state PHL. In addition, most testing performed under the aegis of the multi-site certificate is done by nurses, generally with no formal laboratory training.

While explaining laboratory QA to non-laboratorians working within an alternate professional paradigm can be challenging, participants have found ways to hold local staff accountable for their performance. The most common practice in this regard is the designation of an *on-site program coordinator* with specific duties.

Some focus group participants expressed a preference for cross-training staff that already have some

laboratory exposure, such as a phlebotomist or other staff who have both the capability to perform the job functions and have demonstrated an interest in laboratory work. All, however, agreed that in laboratories doing moderately complex testing, the site coordinator must be able to meet certain responsibilities, including, at a minimum:

- Assessing quality control (QC) and taking corrective actions, if needed.
- Writing laboratory policies and procedures.
- Managing overall QA, based on an understanding of the “big picture.”

Some suggested that career paths for medical technologists could include the position of *site coordinator* or *laboratory manager* for facilities performing LPHT, including some moderate complexity testing.

The Kentucky Division of Laboratory Services (DLS), which oversees 346 local testing sites, created the position of *co-director* at each local health agency on the multi-site certificate. The co-director is listed as one of several testing personnel on the CLIA certificate, but in practice is also tasked with maintenance of QC records—“our eyes on-site,” according to the technical consultant for the program. At sites doing moderate complexity testing, the state asks that the co-director have at least a bachelor's degree, and often the designated person is the local director of nursing.

In Delaware, the entire public health system is state-owned and state-operated, creating an opportunity for more direct control. The Delaware Public Health Laboratory holds one multi-site, LPHT certificate covering 11 sexually transmitted diseases (STD); Women, Infants and Children Nutritional Program (WIC); and family planning clinics. The four sites performing moderate complexity testing are staffed by laboratory technologists who are employees of the state PHL and who report directly to the state laboratory's QA manager, the technical consultant for the multi-site program.

This arrangement ensures competent on-site supervision, accountability and seamless communica-

tion between the four sites performing moderate complexity testing and the state PHL. The drawbacks are finding qualified individuals to assume these positions and the necessity of providing back-up staff when necessary.

#6: Consider the use of a contract to enforce accountability among local sites.

Depending on the regulatory and bureaucratic climate within a particular state, a contract may be a useful tool to formalize the relationship between the state PHL and the local public health sites.

The North Carolina state PHL, for example, has a comprehensive contract governing its relationship with all sites—all autonomous—under four state CLIA multi-site certificates. The contract lists requirements for quality assessment and QC, changes to test menus and more.

For example, the North Carolina contract specifies that any laboratory receiving three sanctions within a two-year period will be automatically removed from the state CLIA contract program (although the contract provides that the relationship can be terminated for any reason). Events prompting a sanction include repeated failure to address a noted deficiency, allowing unauthorized personnel to perform testing, falsifying documentation and using expired reagents.

The contract also requires that an on-site *laboratory manager* be designated to carry out a list of almost two dozen specific responsibilities. And while the contract “highly” recommends that the laboratory manager be either a medical technologist or medical laboratory technician, it mandates that the state technical consultant “review and approve . . . prospective new laboratory personnel *prior* to an offer of hire being extended.”¹⁰

Most currently operating multi-site programs, however, do not use contracts. In Tennessee, a state with a strict laboratory licensure law, state regulations specify that county health department laboratories

can perform up to nine waived tests, but only if they successfully complete a training program offered by the state PHL. This confers some authority on the PHL. “It’s basically a handshake,” said the director for the Tennessee program. “We rely on them to do what they say they’re going to do.”

#7: Consider the use of a policy manual that delineates the responsibilities of the certificate holder and the local testing sites.

A policy manual, whose terms are understood and agreed to by all parties, may protect the PHL from some legal liabilities. For example, the manual may specify that local sites agree to a certain degree of oversight by the certificate holder. It might also outline the conditions for terminating the relationship—generally, any reason with or without cause. If the oversight laboratory has a formal contract with local sites, it can include a provision requiring sites to review and agree to abide by all of the terms outlined in the policy manual, as the North Carolina State Laboratory of Public Health does.

#8: Assure that local sites understand the group consequences of persistent performance deficiencies.

If any one testing site is found to be out of compliance with CLIA regulations, CMS has the option of terminating the entire multi-site program, thus affecting all sites listed on the CLIA certificate. “We’re in the boat together and if the boat sinks, we all sink,” said one focus group participant.

This CLIA rule gives the certificate holder—the state or local PHL—clout to protect the mutual interests of all local testing sites. Several focus group participants noted that knowing that “one bad site can ruin it for everyone,” has the beneficial effect of encouraging regulatory compliance.

#9: Explore various means to communicate with local testing sites remotely, but assure some face-to-face contact.

“As in anything, communication is key,” said one focus group participant.

At a minimum, local testing sites should have e-mail and Internet access so they can research test methods, access QA/QC tools and communicate electronically with the CLIA certificate holder. Sites within the Delaware multi-site program are connected to the state PHL’s laboratory information management system (LIMS).

Regardless of the communications infrastructure, however, focus group participants strongly recommend regular face-to-face contact, including an initial site visit, to develop rapport with local testing staff and to set the stage for meaningful remote communications.

Face-to-face contact especially helps to establish the technical consultant and the PHL as resources that can be readily accessed. “Emphasize that you’re there to help them as much as possible,” advised one participant. “When there is a face-to-face meeting it empowers (local test personnel) to feel that they can call more often,” said another.

The frequency of regular, planned site visits among the programs represented at the Raleigh meeting ranges from annually to quarterly. However, said one participant, “You need to have flexibility and the ability to travel to make additional on-site visits as needed.”

Short of a site visit, some forms of communication will likely work better for different purposes and for different individuals. One consultant, for example, encourages local sites to e-mail her when problems arise so that a printed copy of the e-mail can serve as evidence that the site attempted to resolve the problem.

Other modes of remote communication used by participants include Public Health Information Network satellite downlinking, cell phone and telephone, videoconferencing, a laboratory newsletter, a CLIA certificate program website, blast e-mail, fax,

technical bulletins and periodic surveys to assess training needs. Staff at the North Carolina PHL take digital pictures of miss-packaged laboratory specimens and post them on-line so local sites “know what not to do.”

Finally, in addition to communicating with local testing sites, it is important to communicate with the programs for which the sites are performing testing, such as HIV and STD programs.

#10: Develop a procedure manual and standard forms to facilitate proper QA/QC practices.

The CLIA certificate holder should document all technical procedures, since local testing personnel don’t necessarily have the expertise to do so. Procedures should be maintained in a manual on-site, but may also be posted on the Internet. (The certificate holder may need separate manuals for sites performing some moderate complexity testing and sites performing only waived tests, if testing standards are different.)

The Michigan PHL has a comprehensive website for its regional, CLIA multi-site program that includes the regional laboratory manual, as well as laboratory accreditation tools, a regional laboratory directory and more. (To access the site, go to www.michigan.gov/mdchlab and follow the link to the regional laboratory system.)

Some CLIA multi-site programs have customized standard operating procedures (SOPs) to the specific equipment and reagents used by each site, while others base SOPs on the most commonly used testkits. (See also #12.)

#11: Consider the advantages of using uniform methods across sites and bulk buying.

The use of common methods, and thus common test kits, across sites simplifies training and simplifies the development of a procedure manual. It also per-

mits bulk purchase of test kits, thereby decreasing costs. In some situations this may be more practicable than in others.

#12: Develop a user-friendly quality assurance plan and support it with appropriate forms and oversight.

Overall QA can be a difficult concept to communicate to those without formal laboratory training. It can be especially challenging to try to convert the QA plan “from a piece of paper to a living document that reflects an ongoing process,” as one multi-site certificate laboratory director suggested.

Suggestions to achieve a user-friendly QA plan that is actively implemented include:

- Involving end-users in writing and/or reviewing the plan to assure that it is written to their level of understanding.
- Using terminology that has meaning for end-users (e.g., “occurrence” instead of “out-of-range”).
- Comparing the QA plan to a patient care plan.
- Using the QA plan as a training document.
- Incorporating elements of the plan into standard operating procedures. (See #10.)

Above all, however, focus group participants stressed that having the “right forms” is key to facilitating QA compliance. Most multi-site programs, for example, provide QC forms—either developed de novo or based on the manufacturer’s QC forms—that are periodically reviewed by site coordinators, technical consultants and/or laboratory directors. In most programs, the QC schedule is set by the CLIA certificate holder, at least for moderate complexity tests and often for waived tests as well. Some programs, such as Kentucky’s, allow sites to customize parts of the QC form (after state approval), while others, such as Louisiana, allow no modifications.

The QC form in use in Michigan has columns where users record expected and actual QC results. They must record a “P”—for “pass”—before proceeding onto testing. The forms are reviewed by site coordinators and

then technical consultants and laboratory directors. By determining if there is an upward or downward trend in control values over time, consultants and directors can determine if an instrument is failing.

The Kentucky DLS requires on-site co-directors to conduct periodic record searches to make sure testing documentation is complete. If out-of-range control values are recorded, the co-director can refer to a two-page corrective action form provided by the state PHL to lead staff through an investigation. Appropriate corrective action must then be recorded on the back of the original QC form.

The Kentucky program also requires sites to complete a “change form” if they wish to modify a procedure or to change anything related to the CLIA certificate program—e.g., add a test, add testing personnel, change test methods, change test brands, etc. Changes must be pre-approved at the state level.

The North Carolina State Laboratory of Public Health has developed a monthly QA checklist. Participating counties and an agency QA team must include laboratory personnel on that team, but if there is not a team already in place, the laboratory must establish its own QA committee.

#13: Arrange for regular training classes at the PHL and/or at local sites.

Generally, training should encompass pre-analytical, analytical and post-analytical procedures, as well as a review of the quality assurance plan. It should also address specific problems encountered by local testing sites (as documented by technical consultants, in QC records and/or via site surveys).

Most multi-site programs base training on the tests used by a majority of sites, with customized training—perhaps on-site—for testing staff who have difficulty with certain procedures. The Tennessee multi-site program hosts training classes as many as four or five times each year and offers on-site training for large, high-volume clinics.

The North Carolina PHL offers an ongoing and

varied menu of free or low cost educational courses to which counties participating in the certificate program have access. The majority of the course offerings are held at the PHL in Raleigh, with some workshops offered at locations in the four regions. In order to acquire patient specimens for training purposes, the NC PHL awards coupons for free training to sites for each box of urethral smears submitted.

The Connecticut Division of Laboratories provides training for HIV testing and arranges for representatives of test manufacturers to conduct on-site training for other tests.

#14: Conduct proficiency testing at least annually.

CLIA regulations mandate proficiency testing for all of the moderate complexity tests covered by the multi-site certificate. Multi-site programs can only report one result per analyte for each certificate to CMS for required analytes, regardless of how many laboratories participate in proficiency testing. The state may determine that more than one site doing moderate complexity testing may need to participate in proficiency testing to assure that all of the moderate complexity tests are covered (since every site may not offer every moderate complexity test listed on the certificate). To the extent possible, proficiency tests should be rotated annually among sites performing moderate complexity testing and, in addition, should always be rotated among testing personnel within selected sites.

Beyond the minimum CLIA requirements, it is preferable that all sites doing moderate complexity work undergo some specimen-based testing each year, with comparison of test results among sites. Some programs also arrange for proficiency testing of waived sites for one or more tests.

Proficiency tests may be provided to the site by the CLIA multi-site certificate holder or by an external proficiency test (PT) provider or a combination of the two. If an external provider is used, the tests may

be sent to the certificate holder for distribution to local sites or from the PT provider directly to the sites (although the latter incurs extra costs for shipping and handling).

In Tennessee, each of the three sites performing moderate complexity testing on the state's multi-site certificate purchases its own proficiency tests. Testing is rotated among personnel and leftover specimen used for competency assessment. (See #15 for more on competency assessment.)

The Michigan program conducts proficiency testing twice per year in a program that costs the state about \$10,000 annually. The state PHL contracts with the American Proficiency Institute to provide specimens specific to the test menus at each of the sites on the state's six regional multi-site certificates (for all tests except wet mounts). The sites have 10 days to return completed test results to the laboratory director for grading. Test results are entered by the laboratory director into a spreadsheet that contains the expected results. The spreadsheet will calculate the overall score for each analyte. This program allows comparisons among sites as well as among regions since all of the specimens for each test are identical. A report is sent to each site with information about necessary corrective action, if any, and sites are encouraged to use leftover specimen for competency testing.

The Michigan PHL has developed its own program for wet mount testing using multiple views of three photo micrographs, each containing between one and three items that must be identified. (Since at least 80 percent of challenges must be correct, the greater the number of challenges, the more room for error while still passing the test.) The program aims to be "consistent with what the nurse will be seeing in the clinic." The views are posted on a website on a PowerPoint® presentation that contains instructions and a scoring sheet. The site also contains all of the micrographs previously used for testing, along with critiques. To access the site, go to www.michigan.gov/mdchlab and follow the link to the regional laboratory system.

#15: Assure competency assessment at least annually.

Competency assessment goes beyond proficiency testing. It assesses the entire chain of events from pre- to post-analytical activities, including specimen collection, QC, problem-solving skills and more. At a minimum, it involves direct observation of an individual performing a test—including pre- and post-analytical activities—and a review of QC documentation.

Focus group participants recommend the use of a competency assessment checklist that is based on training forms. All of the multi-site programs represented at the Raleigh meeting allow on-site testing staff to conduct the annual competency assessment for procedures in which the peer-reviewers are themselves proficient and perform regularly. If there are not two staff members performing a certain test, e.g., wet mounts, either the technical consultant or the laboratory director for the certificate must conduct the competency check or arrange for an appropriately qualified individual to do it.

Regardless of who conducts the assessment, it and all corrective actions and follow-up activities should be well documented and the documentation reviewed by the technical consultant and/or laboratory director for the certificate. Individuals who perform poorly should receive appropriate training and be re-assessed. Those who consistently perform poorly may need to be removed from the list of authorized testing personnel, at least temporarily.

Some multi-site programs do not require competency assessment for staff who perform only waived testing, but generally do provide them with performance checklists so that they can conduct their own competency checks.

The Kentucky DLS holds the site coordinators or “co-directors” responsible for competency checks that are conducted semiannually for sites doing moderate complexity work and annually for waived sites. Assessments are based on checklists provided by the PHL for each procedure in use. When deficiencies are

found, the PHL offers ideas for additional training.

#16: Conduct internal audits of local test sites at least annually.

The audit should include chart reviews and assess “everything that’s going on that’s lab-related;” in effect, a trial CLIA inspection, often with an inspection checklist.

Audits, however, should not be framed as confrontational encounters. “You’re not there to find problems,” said one focus group participant. “You’re there to resolve issues.” To put audits in the best light, technical consultants may wish to call them “site visits” or “lab surveys to prepare for CLIA inspections,” rather than “inspections” in and of themselves.

When deficiencies are found, corrective action, follow-up and documentation of the entire process are essential. Technical consultants may wish to share among all sites the top 10 deficiencies found during the internal audits, as well as recommended corrective actions. The technical consultant for the Delaware Public Health Laboratory’s multi-site program conducts semiannual inspections of sites doing moderate complexity work and disseminates an aggregate report to local health agency directors “so everyone sees everything.”

The Kentucky DLS plans to experiment with the approach used by the College of American Pathologists, using a team of medical technologists to conduct an annual audit to assess quality assurance and QC using comprehensive checklists.

#17: Be on-site for formal CLIA inspections.

Focus group participants have found that sites generally have advance notice of upcoming CLIA inspections. To the extent possible, they recommend that the technical consultant or laboratory director for the certificate arrive at the site ahead of the surveyors and remain on-site throughout the inspection. Often, inspectors will “zero in” on different elements from inspection to inspection and/or “ratchet up the stan-

dards” as sites become more proficient. Some programs develop a list of post-inspection suggestions—shared among sites—even if the inspections are good.

Summary

The members of the focus group are enthusiastic about how well the LPHT multi-site program is working in each of their states. The recommended practices listed above are a composition of the practices currently in use and those that were suggested to improve on current practices. Many in the group plan to incorporate practices learned at this meeting into their programs. Next steps will be to follow up with the current group to see what changes have been made as a result of this discussion and how they have improved quality and to collaborate on mechanisms to share documents and templates to assist those currently with an LPHT multi-site certificate or those states thinking about the LPHT multi-site certificate.

Acknowledgements

Focus Group Members

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Endnotes

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