By Karen Appold

In Part One of this article, which appeared in the January/February issue, we began a discussion about the qualifications required when a new individual is needed to assume the laboratory director position. Planning ahead will make transitioning from one laboratory director to another an easier task. A non-waived laboratory cannot operate, even for one day, without a qualified laboratory director.

In addition to education qualification requirements (discussed in Part One), laboratory training is necessary to serve as a laboratory director. Therefore, if a candidate does not possess the necessary training/experience to qualify, he could act as a “co-director,” working beside the qualified laboratory director for a year (or two years for high complexity), and then take over, explained Anita Coleman, BS, MT(ASCP), Technical Support Specialist, COLA. Obviously, this requires advance planning and documentation to prove the experience was acquired.

Individuals who become directors by this route must be able to show documentation of functioning as a co-director if asked during a laboratory inspection. The inspector will check the qualifications and can require the laboratory to cease testing if the laboratory director is unqualified. “Unfortunately, COLA sees this more often than not, especially in newly enrolled laboratories,” Coleman said.

Coleman believes this is the case because when starting a new laboratory, physicians may be unaware of CLIA qualifications for laboratory directors. As a result, Centers for Medicare and Medicaid Services (CMS) is now checking on a laboratory director’s qualifications prior to issuing a CLIA Certificate of Registration, Compliance, or Accreditation. To prevent problems, Coleman recommended that prior to opening a laboratory, a physician enlist the help of a technical consultant who knows where to find information on laboratory director qualifications.

“The good news is that once qualified, a laboratory director is qualified for life,” said Verlin Janzen, MD, Laboratory Director, Hutchinson Clinic.

“Presently, there aren’t any requirements for recertification.”

Courses and Other Offerings

To assist with succession planning and dealing with a laboratory director vacancy, consider COLA’s conferences and online course offerings.

To become director of a moderate complexity laboratory, a physician who does not qualify by other means must complete an approved program which totals 20 hours of CME credits. COLA offers the COLA Symposium for Clinical Laboratories which includes a laboratory director qualification track. Usually COLA has two conferences annually that present this track.

COLA also has an approved online laboratory director course program through its LabUniversity® to meet this requirement. The University of Iowa also offers approved online courses.
As a physician and HIV/AIDS researcher and educator, I work with dedicated laboratorians who are at the heart of my medical investigation teams. National Medical Laboratory Professionals Week is a good time to recognize the critical role laboratory professionals play on health care teams across the nation. I thank my laboratory colleagues for their collaboration and quality service, and encourage you to do the same.

There are many ways to celebrate Lab Week, and you may want to consider the benefits of continuing education as an investment in yourself and your future. To coincide with the upcoming COLA Symposium for Clinical Laboratories in Dallas, this issue includes an article about getting the most out of attending a laboratory conference. I will be presenting HIV Diagnosis and Treatment: The Importance of Laboratory Medicine, and there are many other relevant topics and knowledgeable speakers that can benefit you in your chosen field of laboratory medicine.

Also in this issue is Part 2 of the article about succession planning. Armed with knowledge of the qualification requirements and responsibilities of the laboratory director, you can plan ahead for this significant personnel change.

Again, thank you to all laboratory professionals and I hope to see many of you in Dallas.

Donna E. Sweet, MD, MACP
Chair, COLA Board of Directors
Succession Planning: Filling a Laboratory Director’s Shoes Part Two — continued from page 2

- If the laboratory hired a BS or MS educated medical technologist to perform laboratory testing who also has the required experience, then he or she meets the requirements.

- If the laboratory finds a qualified candidate, he or she needs to understand the responsibilities for the laboratory’s overall operation and administration. However, it is acceptable to delegate some of the responsibilities to a qualified individual.

For a high complexity laboratory, replacing a laboratory director will require more planning to achieve the necessary experience if a fellow qualified staff physician can not step in. “I suggest checking with a local hospital for a pathologist to become a laboratory director at least in the interim while a qualified physician is trained,” Coleman said.

Filling Shoes with Little Time to Shop
COLA has experienced two unfortunate situations firsthand. In one instance, the laboratory director at a COLA laboratory died suddenly. Another time, the laboratory director was too ill to continue working. In both of these instances, someone needed to assume the reins immediately.

When situations like these occur, Coleman advised contacting the local medical community. “There may be a laboratory director at a neighboring facility who is willing to help out until a replacement can be found,” she said. “A local hospital, national certification agency, or state agency may be able to provide assistance in locating a permanent replacement. It may be necessary to stop testing for a few days or weeks until a solution can be found.”

Other options for the short-term might include a qualifying partner, perhaps one who directed a laboratory prior to CLIA implementation, or a consultant who is a medical technologist.

Resources at Your Fingertips
COLA has a lot of resources on its Web site as well as experienced personnel available to consult, educate, and guide a laboratory through the process of filling a laboratory director vacancy. “COLA gives laboratories and laboratory directors the tools they need to succeed,” Coleman concluded.

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Additional Information
COLA: www.cola.org or www.labuniversity.org
University of Iowa:
www.medicine.uiowa.edu/cme/clia
CLIA Brochure #7:

New LabU Discount Offer!

We are all looking for ways to make our dollars go further, and in this issue, COLA will be offering a discount on a selected LabUniversity on-line course. For March/April we are offering a 30% discount on:

Laboratory Director Responsibilities

That’s double the normal 15% discount that COLA members receive when purchasing LabUniversity courses!

You can purchase Laboratory Director Responsibilities from the COLA Store at www.cola.org. At checkout enter the discount code: LDR30 to receive the discount. This discount code is valid for purchasing the Laboratory Director Responsibilities course until May 15, 2009.
Planning ahead enables you to schedule sessions, set times to meet colleagues and determine how to spend your time in the exhibit hall.

By Karen Appold

Although attending a conference can be expensive and time consuming, it can be educational, worthwhile and enjoyable if everything goes right. To ensure you make the most of your time away from the lab, it’s important to start planning for your trip at least several months ahead.

Janie Roberson, SCT(ASCP), IAC, cytology supervisor, University of Alabama at Birmingham, says she reviews the conference package and program early and carefully. “I prioritize activities because it is usually impossible to attend all events,” she said. She also registers early, which saves money on registration fees and increases the likelihood that she can attend sessions she wants most.

Planning ahead also applies to making travel arrangements. Roberson usually stays at the hotel where the conference is held. She books a room early because room blocks may sell out quickly. This will save time and money on transportation to and from the conference and it is more convenient if meetings last into evenings.

In addition, Roberson oftentimes plans to meet colleagues before arriving at the conference to discuss details of ongoing projects or committee work. This allows face to face interaction, which she prefers rather than a conference call.

Deciding which conferences to attend is an easy task for Roberson. There are two national organizations for cytology: The American Society for Cytotechnology (ASCT) held in spring and The American Society of Cytopathology (ASC) held in autumn. “I attend these conferences because they focus on my field and offer the best opportunities to interact with other cytology colleagues,” Roberson said. As a supervisor, Roberson chooses sessions on management and new technology because they provide the greatest benefits and application to her position.

To use her time wisely in the exhibit hall, Roberson visits vendors who carry products that may have use in her lab. “I spend in-depth time at a few during each break,” she advised. “And, I pick up materials which are less applicable to the cytology laboratory.”

Because her time is limited, Roberson usually doesn’t take advantage of local tourist trips. However, if the venue is interesting, she may stay an extra day. “It is nice to have trips arranged for spouses and others who accompany attendees,” she added.

After returning home, Roberson uses the information she acquired. She adds business cards and e-mail addresses to her files and posts handouts and materials for other laboratorians to review.

Strategies to Save Money

Terri Wallis, MBA, MT(ASCP), safety coordinator, TriCore Reference Laboratories, Albuquerque, NM, has also found that planning ahead enables her to accomplish more while at a conference.

Prior to attending a conference, Wallis studies lists of sessions to organize her time. “If I am going with co-workers, then we coordinate so we attend different sessions,” she said. Classes that provide technical information are a top priority, followed by courses that address the human side of work.
If vendors exhibit, Wallis determines which ones she wants to see so she can locate them first. She also contacts colleagues to see if they are attending, so they can plan to meet during the conference.

Wallis attends conferences to learn new information and renew her enthusiasm. "I get a big charge out of attending national meetings," she said. "They stimulate my brain with new ideas on how to improve my job."

Wallis attends conferences which are closest to home to save money and chooses those that offer useful and pertinent information. She prefers to stay at the conference hotel, so she won’t have to rent a car. Usually, she doesn’t attend local tourist trips because interesting sessions occupy her time. If she has time, she'll find a colleague to join her on an informal tourist tour.

When she returns to the lab, Wallis organizes material she gathered at the conference and passes it onto colleagues. "My director asks me to present what I have learned to the staff in our department," she said. "If something has broader appeal, then I will set up a class for all employees."

**Personal Preparation**

When attending a conference, Kimberley Smith, research lab assistant, Swedish Medical Center, Center for Perinatal Studies, Seattle, WA, hopes to learn new technologies and techniques, make contacts and learn different approaches to stress in the workplace.

To put herself in a better position to accomplish these goals, she studies the latest techniques and gets plenty of rest prior to the event so she can be alert and pleasant.

Smith chooses conferences with the most pertinent information to her field and those with wide ranges of topics. These same criteria apply to choosing sessions and special events. To make the most of her time in the exhibit hall, Smith tours the booths and asks questions when she needs more information or details.

When she returns home, Smith reflects on the information she learned and shares it with colleagues.

**The Benefits of Planning Ahead**

Just like a family vacation, attending a conference requires significant planning to ensure a smooth journey and experience. By starting to make arrangements months ahead of time, you won’t be so overwhelmed in the days preceding your departure. And, once you arrive, you can simply follow the agenda you’ve already established for yourself.

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LABORATORY DIRECTOR RESPONSIBILITIES, PART 2

The Succession Planning article stresses the importance of finding a qualified laboratory director. When a change in laboratory director occurs in a non-waived lab, it is also a good time to review the responsibilities of the laboratory director, and to verify that those responsibilities are being met. The laboratory director is responsible for the overall operation of the lab and the competency of all laboratory personnel. In the previous issue of Insights, Part 1 of this reminder listed the General and Procedural responsibilities of the lab director. The lab director is also responsible for the following:

Personnel Responsibilities

- Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise, and accurately perform tests and report test results.
- Ensure that prior to testing patients’ specimens, all personnel have the appropriate education and experience, and receive the appropriate training for the type and complexity of services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.
- Have a written list of responsibilities for each individual in the laboratory that specifies the level of activity each is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.
- Ensure that policies and procedures are established for monitoring individuals who conduct pre-analytical, analytical, and post-analytical phases of testing to verify that they maintain competency to:
  - Process specimens
  - Perform test procedures
  - Report test results promptly and proficiently
- Whenever necessary, identify needs for remedial training or continuing education to improve skills
- Ensure that a general supervisor provides on-site supervision of high complexity test performance by specified testing personnel

Proficiency Testing Responsibilities

- Ensure that the laboratory is enrolled in an approved proficiency testing (PT) program
- Ensure that PT samples are tested in the same manner as patient samples
- Ensure that PT results are returned on time to the PT program
- Ensure that PT results are reviewed by the appropriate staff and the corrective action plan is followed when PT results are found to be unsatisfactory

Quality Control Responsibilities

- Ensure that quality control and quality assessment programs are established and maintained to identify failures in quality as they occur
- Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system
- Ensure that remedial actions are taken and documented whenever significant deviations from the laboratory’s established performance characteristics are identified, and patient test results are reported only when the system is functioning properly
COLA Salutes Medical Laboratory Professionals During Lab Week!
April 19-25, 2009

National Medical Laboratory Professionals Week (NMLPW) is a time of recognition for the nation’s medical laboratory professionals who play a critical role in the delivery of quality health care. The first official observance of National Medical Laboratory Week was in 1975. In 2006, the name was changed to National Medical Laboratory Professionals Week. The addition of Professionals was made to acknowledge that all the technological advances and sophisticated instrumentation cannot take the place of the people. That’s you, the laboratory professional, and this week is about the respect and recognition you deserve all year.

Many things have evolved in our field over the years, and clinical laboratory testing plays an ever increasing role in the detection, diagnosis, and treatment of disease, and in the monitoring of health. Laboratory testing helps people in every stage of life, and almost everyone will have laboratory tests during their lifetime. An estimated 7–10 billion laboratory tests are performed each year in the United States, and it is estimated that laboratory test results influence approximately 70% of medical treatment decisions. That’s a lot of responsibility, and NMLPW celebrates your significant contributions to laboratory medicine!

Medical laboratory technologists, technicians, and other laboratory professionals work diligently to perform pre-analytical tasks like collecting patient blood samples, all specialties of laboratory testing, and ongoing quality control and quality improvement activities. Nationally, there are approximately 300,000 medical laboratory professionals, and this week celebrates who you are and what you do everyday.

It’s all about serving the patients and clinicians, but some of you don’t get the opportunity to interface with the patients and clinicians who rely on your expertise. Lab Week recognizes that you are a vital link in the provision of effective health care and patient safety, even when you remain behind the scenes.

Your dedication and commitment to quality, accuracy, and service directly and positively impacts patient care, and COLA would like to take this opportunity to say THANKS FOR ALL YOU DO!
Come to The Symposium for Clinical Laboratories
May 6–9, 2009
The Fairmont Hotel Dallas

To learn more visit www.cola.org or call 1.800.981.9883.

Laboratorians: Saving Lives
One Test at A Time
A COLA 20th Anniversary Campaign

We invite you to join our community and help show others how the contributions of laboratorians are saving lives... one test at a time. Begin by ordering your FREE WRISTBAND with COLA’s campaign slogan at www.cola.org/20th/registration.html. We look forward to your support and participation.