

# INSIGHTS

## SUCCESSION PLANNING: FILLING A LABORATORY DIRECTOR'S SHOES PART ONE

*By Karen Appold*

When someone leaves a laboratory director position, or any job for that matter, it could be for a myriad of reasons. He accepted another position; she is moving out of town; he is retiring; she became terminally ill; he died unexpectedly. In some cases, especially when enough notice is given, it is possible to smoothly transition to hiring a replacement. Other times, particularly when someone is suddenly unable to do a job, it can be challenging to fill the vacancy with a qualified individual in a timely manner.

In either case, planning ahead will make transitioning from one laboratory director to another an easier task. According to Verlin Janzen, MD, Laboratory Director, Hutchinson Clinic, the best way to ensure a smooth transition is to have more than one physician involved in and knowledgeable about the laboratory. In that scenario, one physician could be named assistant laboratory director or co-director. That individual should actively work to obtain the appropriate training and experience to be qualified as a laboratory director and participate in meetings and oversight of operations. This way, if the current laboratory director is unable to fulfill his or her responsibilities, the trained physician can step in immediately. It is imperative that someone can do this because a non-waived laboratory cannot operate, even for one day, without a qualified laboratory director.

Be sure to take advantage of any advance notice. "As soon as the laboratory director sets a termination date, start the transition process to a new laboratory director," advised Tim Dumas, CLS, Medical Laboratory Consultant, Tim "The Lab Guy" Consulting. "It

should be a joint effort between the out-going director, the candidate for new director, and the laboratory manager, who should take a big role in ensuring a smooth transition."

Some of a laboratory manager's roles during this time, according to Dumas, will be to:

- Verify that the incoming director is qualified under The Clinical Laboratory Improvement Amendments (CLIA) rules;
- Notify CLIA/COLA of the change in directorship;
- Organize the procedure and policy manuals to be read by and then signed by the new laboratory director; and
- Introduce the new laboratory director to laboratory staff.

### Consider the Responsibilities

Keep the laboratory director's responsibilities in mind when searching for a replacement. Ultimately, the laboratory director is responsible for the overall operation and administration of the laboratory. He or she must ensure that the laboratory provides accurate, reliable, and timely testing services. This individual will work with physicians who order tests and with nursing and administrative personnel to be the "face" of the laboratory. Responsibilities fall into these categories: procedural, personnel, proficiency testing, quality control, and quality assessment.

During an onsite regulatory inspection, the inspector will look for evidence of active involvement by the laboratory director in the laboratory's daily operations.

*Continued on page 2*



## SUCCESSION PLANNING

**FROM THE CHAIR** Change is all around us, and we don't always plan for change like we should. In this issue is Part One of an article about succession planning. Every laboratory should have a plan for how they would replace their laboratory director with another qualified individual, if and when the need arises. This is an important consideration, because a clinical laboratory cannot operate for even one day without a qualified individual at the helm.

Also in this issue is the COLA Patient Safety Goal for 2009. COLA began the Patient Safety Program in 2008. This program focuses on improving areas in laboratory medicine that are found to have high error rates and significant impact on patient safety. Learn about this important patient safety goal, and begin taking steps to ensure compliance and subsequent improved patient outcomes in your laboratory.

**Donna E. Sweet, MD, MACP**  
Chair, COLA Board of Directors

*Succession Planning: Filling a Laboratory Director's Shoes*  
*Part One — continued from front cover*

For a comprehensive document on a laboratory director's responsibilities (COLA LabGuide #3), go to COLA's Web site, click on "Member Site," and then go to Educational Resources. Another option to obtain this information is CLIA Brochure #7, available on the CLIA Web site.

**Sizing Up Educational Requirements**

Several different sets of qualifications will enable someone to become a laboratory director. Keep in mind that educational requirements for a laboratory director differ depending upon the laboratory's complexity. Additionally, all candidates must have a laboratory director license if required by the state. A laboratory director may not direct more than five non-waived laboratories simultaneously.

Qualification requirements for director of a moderate complexity laboratory:

- A licensed MD, DO, or DPM who is either certified in anatomic or clinical pathology or has one year of laboratory training or experience directing or supervising non-waived testing. If the licensed MD, DO, or DPM does not meet the above criteria, the candidate would need to earn at least 20 CME credits in laboratory practice about director responsibilities. The candidate would also qualify if training equivalent to 20 CME credits was obtained during medical residency, explained Anita Coleman, BS, MT(ASCP), Technical Support Specialist, COLA.
- A candidate who has obtained a doctoral degree (PhD) in laboratory science with one year experience directing or supervising non-waived testing would qualify.
- An individual could also qualify by obtaining a master's degree in laboratory science and one year laboratory training or experience and one year of supervisory experience. Or, a candidate could qualify by obtaining a bachelor's degree in laboratory science and two years laboratory training or experience and two years of supervisory experience.

*Continued on page 3*

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Succession Planning: Filling a Laboratory Director's Shoes Part One — continued from page 2

- If prior to February 28, 1992, the candidate was qualified under state law or Medicare laboratory regulations as a director, this individual would be grandfathered in as a laboratory director.

Qualification requirements for director of a high complexity laboratory:

- A licensed MD, DO, or DPM who is certified in anatomic or clinical pathology. If the licensed MD, DO, or DPM is not certified in anatomic or clinical pathology but had one year of laboratory training during medical residency, he or she would qualify. If the licensed MD, DO, or DPM is not certified in anatomic or clinical pathology, but has two years experience directing or supervising high complexity testing, the candidate would qualify, Coleman said.
- A candidate who has obtained a doctoral degree in laboratory science and is board certified (by a board approved by the U.S. Department of Health and Human Services) in the specialty/subspecialty of the laboratory's service that makes it high complexity would qualify. Until February 24, 2003, in lieu of board certification a PhD candidate could have qualified with at least two years of laboratory training or experience, and two years experience directing or supervising high complexity testing.

- If prior to February 28, 1992, the candidate was qualified under state law or Medicare laboratory regulations as a director, this individual would be grandfathered in as a laboratory director.

### 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.

*Look for the continuation of this article in the next (March/April) issue. Part Two discusses other ways to qualify and ways to find the right lab director for your lab.*

### Additional Information

COLA: [www.cola.org](http://www.cola.org) or [www.labuniversity.org](http://www.labuniversity.org)

CLIA Brochure #7:  
[www.cms.hhs.gov/CLIA/downloads/brochure7.pdf](http://www.cms.hhs.gov/CLIA/downloads/brochure7.pdf)

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**SPECIAL**

## New LabU Discount Offer!

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

### Laboratory Personnel Requirements

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

You can purchase Laboratory Personnel Requirements from the COLA Store at [www.cola.org](http://www.cola.org). At checkout enter the discount code: **PER30** to receive the discount. This discount code is valid for purchasing the Laboratory Personnel Requirements course until **March 15, 2009**.

Look for other discounted courses in upcoming issues of Insights. We want to help keep continuing education affordable for labs!



## COLA PATIENT SAFETY PROGRAM

### PATIENT SAFETY GOAL FOR 2009: SPECIMEN IDENTIFICATION

COLA began the COLA Patient Safety Program in 2008. This program focuses on areas in laboratory medicine that are found to have high error rates and significant impact on patient safety. COLA will identify an existing COLA criterion or create a new COLA criterion as the patient safety goal for each year, and provide education on good laboratory practices for implementation of that criterion. The program has been integrated into the COLA survey process.

The COLA Patient Safety Goal for 2009 is:

*PRE 17: Are all specimens labeled with a unique patient identifier composed of 2 individual identifiers, and the source of the specimen (when appropriate)?*

To contribute to the reduction of medical errors as a result of misidentification, it is necessary for laboratories to ensure that all specimens are labeled with unique identification that can be linked to the patient, the requisition, and the report. Using a combination of two identifiers increases the likelihood of catching misidentifications due to common or similar names. It is also important to include the source of the specimen on the label, when appropriate. For example, the source is obvious for collected tubes of blood, but a swab would need to be labeled as throat, wound, etc. to identify the source.

Proper patient identification (which was the Patient Safety Goal for 2008) followed by proper specimen labeling is an essential part of the pre-analytic process. Laboratories need to be aware of the emphasis in the medical community to reduce medical errors due to mislabeled specimens. A successful mechanism is to utilize at least two identifiers on the specimen and to carefully label the specimen immediately after collection. Do not pre-label collection tubes or specimen containers.

Appropriate identifiers include:

- Name
- Birth date
- Medical record number
- Social security number

Bar-coding technology is becoming quite sophisticated, and in some settings may be part of the specimen labeling system. While barcodes can create unique identification, there is still an opportunity for error if the barcode is not matched to the proper specimen. In this circumstance, using a second identifier beyond the barcode could help to prevent identification errors and subsequent specimen labeling errors.

Verify that the same identifiers are present on all of the following that are applicable:

- Requisition (order)
- Patient wristband
- Patient chart
- Barcodes
- Sample labels

Correct specimen identification across the path of workflow is critical. The specimen must retain its unique identification when transferred to other containers for testing. Test results performed on mislabeled specimens will be linked to the wrong patient, and may put the health of two patients at risk.

Think about this important patient safety goal, and take steps to ensure compliance in your laboratory.

**Want to Learn More  
About Preventing  
Pre-analytic Errors?**



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**Top 10 Pre-Analytic Errors**  
at the COLA Symposium for Clinical Laboratories  
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## LABORATORY DIRECTOR RESPONSIBILITIES, PART 1

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. For Part 1 of this reminder, we list the General and Procedural Responsibilities of the lab director. In the next issue, Part 2 will list the Personnel, Proficiency Testing, and Quality Control Responsibilities.

### General Responsibilities

- Must be accessible to the laboratory to provide onsite, telephone or electronic consultation as needed
- Direct no more than five labs
- Ensure the physical plant and conditions are appropriate for the testing performed and provide an environment safe from physical, chemical, and biological hazards
- Ensure compliance with applicable regulations
- Verify that delegated responsibilities are properly performed

### Procedural Responsibilities

Ensure that:

- Test systems provide quality laboratory services for pre-analytic, analytic, and post-analytic phases of testing
- Test methods selected are capable of providing quality results
- Verification procedures used are adequate to determine accuracy, precision, and other pertinent performance characteristics of the method
- Test result reports include pertinent information required for interpretation
- Consultation is available to the laboratory's clients about the quality of test results reported and their diagnostic interpretation
- An approved procedure manual is available to all personnel
- Laboratory personnel are performing the tests as required for accurate and reliable results

Look for Part 2 in the next issue of Insights.

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