Successful Laboratory Leadership: Taking Action and Getting Results
Delegation and Competency Assessment in the Laboratory

Types of Delegation

1. CLIA-delegated responsibilities
2. Delegating as a leader (ie, tasks and responsibilities delegated for projects or when the laboratory medical director (LMD) is unavailable)

CLIA Delegation Responsibilities

The LMD can delegate some responsibilities but remains "ultimately responsible and must ensure that all duties are properly performed and applicable CLIA regulations are met." CLIA-delegated responsibilities must be in writing. The following information is from the CLIA brochure **Laboratory Director Responsibilities**.

The LMD must:

1. Ensure testing systems provide quality services during the preanalytic, analytic, and postanalytic phases and are appropriate for the patient population.
2. Ensure the laboratory's physical and environmental conditions are adequate and appropriate for the testing performed.
3. Provide an environment safe from physical, chemical, and biological hazards, and ensure safety and biohazard requirements are followed.
4. Ensure a general supervisor (high complexity testing) is available to provide day-to-day supervision of all testing personnel and reporting of test results and provide on-site supervision for specific minimally qualified testing personnel when they are performing high complexity testing.
5. Retain sufficient numbers of appropriately educated, experienced, and/or trained personnel to provide consultation, properly supervise, and accurately perform tests and report test results in accordance with the written duties and responsibilities specified by you.
6. Assure new test procedures are reviewed, included in the procedure manual and followed by personnel.
7. Ensure each employee's responsibilities and duties are specified in writing.

The LMD may:

1.Delegate, **in writing**, to a **clinical consultant** the responsibilities for ensuring:

- Test reports include pertinent information for test interpretation, and
- Availability for consultation concerning test results and the interpretation of those results as they relate to specific patient conditions.

2. Delegate, **in writing**, to a **technical consultant** (moderate complexity) or **technical supervisor** (high complexity) the responsibilities for ensuring:

- Appropriate test method selection;
- Adequate method verification to determine the accuracy and precision of the test;
- Enrollment of the laboratory in a CMS-approved proficiency testing (PT) program for the test performed;
- PT samples are tested in accordance with the CLIA requirements;
- PT results are returned within the time frames established by the PT program;
- PT reports are reviewed by the appropriate staff;
- Corrective action plans are followed when PT results are found to be unacceptable or unsatisfactory;
- Quality assessment and quality control programs are established and maintained;
- Acceptable analytical test performance are established and maintained for each test system;
- Remedial actions are taken and documented when significant deviations from the laboratory's established performance characteristics are identified, and patient test results are reported only when the system is functioning properly;
- Personnel have been appropriately trained and demonstrate competency prior to testing patient specimens;
- Policies and procedures are established for monitoring personnel competency in all phases (preanalytic, analytic, and postanalytic) of testing to assure the ongoing competency of all individuals who perform testing;
- Remedial training or continuing education needs are identified and training provided; and
- An approved procedure manual is available to all personnel.

3. Delegate, **in writing** to a **general supervisor** (high complexity), the responsibilities for assuring:

- Remedial actions are taken when test systems deviate from the laboratory's established performance specifications;
- Patient test results are not reported until all corrective actions have been taken and the test system functions properly;
- Orientation is provided to all testing personnel; and
- Annual personnel performance evaluations and documentation of testing personnel performance competency.

As the LMD, you must monitor the conditions in the laboratory and ensure a quality management plan:

1. Ensure effective communication among management.
2. Review quality control and quality assessment methods.
3. If no problems are identified through quality control or quality assessment programs, investigate the need for more stringent or sensitive programs.
4. Ensure quality assessment activities include a mechanism for resolution for complaints received.
5. Ensure quality assessment activities include a mechanism to address breakdown in communication between the laboratory and those authorized to order tests and receive test results.
6. Review sample of PT results; ensure PT samples are tested in same manner as patient specimens and the cause of PT failures is identified, corrected, and documented.
7. Ensure lab staff and management are aware of CLIA requirements that preclude them from referring PT specimens to another lab or communicating about the results until after the date when the lab must report PT results.
8. Review a sampling of results obtained from procedures and their outcomes to verify accuracy of tests for which PT is not required.
9. Review policies and procedures for personnel evaluation and sampling of personnel evaluations.
10. Review a sampling of analytic performances of test systems for acceptability.

Reference:
Clinical Laboratory Improvement Amendments (CLIA), Dept of health and Human Services, Centers for Medicare and Medicaid Services. Laboratory director responsibilities. Published August 2006.

Delegating as a Leader

Rewarding Delegation
Most of the time the work you have delegated will be correct and you can agree that the person has done a good job. Don't keep this a secret. Tell the person this by stating what is good about:

- The final results.
- His or her achievement.
- His or her performance of the task.

When to Delegate
Generally, you should delegate work to someone else if:

- The work is not confidential or sensitive.
- The other person has most or all of the skills needed.
- The other person will benefit from the delegation by learning something new.
- The work will recur in the future so your investment in delegating and training will pay off.

When you delegate, ensure you devote enough time to explain the work, train as needed, supervise, and answer questions.

Delegation Mistakes
Even with the best plans, delegation can still go wrong. Examples include:

- Failing to delegate enough of your work to others
- Rushing into delegating without identifying the final product
- Changing the projects specifications part-way
- Micromanaging
- Failing to set up check points for monitoring the work project progress
- Failing to give feedback on work product mile
- stones or final deliverables
- Delegating to the wrong person
- Failing to provide sufficient authority to the delegatee to act and to get others to act
- Failing to hold the delegatee accountable for the results within their power to achieve
- Delegating things that are beyond the other person's power to achieve

Correction
If you have delegated the work properly, the work should get completed as expected, but what if it isn't? You have several choices, depending on the amount of time available:

1. Correct misunderstandings about what was needed, point out exactly what is wrong, and have the delegated person correct it.
2. Allow more time and provide more resources, perhaps even a consultant.
3. Assign the work to someone else who can do the work.
4. Do the work yourself.
5. Abandon getting the work done.

How to Delegate

1. Describe the desired outcome, due date, and factors for evaluating results.
2. Describe how the work will impact financial rewards, future opportunities, informal recognition, and other desirable consequences.
3. Specify the degree of authority and independence this role will have. Will the individual need to:
    - Wait to be told what to do.
    - Ask what to do.
    - Recommend what should be done, and then wait for approval.
    - Recommend what is going to be done, and then act.
    - Take action and report this immediately.
    - Take independent action and report periodically.
4. Give the person the big picture, so that decisions and adjustments can be made when something unexpected happens and you are not available.
5. Identify constraints and boundaries.
6. Don't tell the other person how to do the work unless there is some mandated procedure.
7. Specify the frequency for any applicable progress reports and when you should review the work (eg, at each stage).

Deciding on the Person

When delegating, ensure the person you are delegating responsibilities to is independent enough to get the job done with little supervision, and contains the knowledge and skills necessary to accomplish the tasks. Keep in mind:

- Does the work align with the person's long-term goals and need for development toward those goals?
- Does the person have the time to take on the additional work? Or will major work reassignments be necessary?
- Does the person have an interest in the work?
- Does the person have a history of meeting deadlines?

CLIA Competency Assessment Requirements

CLIA competency assessments vary by role as described in this chart:

Role	Competency Assessment Based on Federal Regulatory Responsibilities	Competency Assessment Includes Six Required Procedures
Clinical consultant	Yes	No (unless also perform testing)
Technical consultant	Yes	No (unless also perform testing)
Technical supervisor	Yes	No (unless also perform testing)
General supervisor	Yes	No (unless also perform testing)
Testing personnel	Yes	Yes

Competency Assessment Timeline

- Employees should be assessed at six months, one year, and annually thereafter.
- Assessments must be documented.
- If the test methodology or instrumentation changes, an individual's competency must be reevaluated to include the use of the new test methodology or instrumentation prior to reporting patient test results.

Six Elements of Competency Assessment for Testing Personnel

The following are the minimal regulatory requirements for assessment of competency for all personnel performing laboratory testing:

1. Direct observations of routine patient test performance, including as applicable, patient identification and preparation and specimen collection, handling, processing, and testing.
2. Monitoring the recording and reporting of test results, including as applicable, reporting critical results.
3. Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.
4. Direct observation of performance of instrument maintenance and function checks.
5. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples, or external proficiency testing samples.
6. Assessment of problem-solving skills. (This can include observing how problem logs and QC logs are handled as well as written tests.)

Reference:
Clinical Laboratory Improvement Amendments (CLIA), Dept of Health and Human Services, Centers for Medicare and Medicaid Services. What do I need to do to assess competency? Published November 2012.

Corrective Action

If an employee fails to demonstrate satisfactory performance on the competency assessment or has not responded sufficiently to the informal feedback just described, it is necessary to take develop a corrective action plan and document progress.

Ongoing Professional Practice Evaluation (OPPE) and Focused Professional Practice Evaluation (FPPE)

- OPPE is a screening tool to evaluate practitioners who have been granted privileges and to identify clinicians who might be delivering unacceptable quality of care.
- FPPE is a follow-up to the process to determine the validity of any positives found through OPPE.
- Example measures for OPPE and FPPE that may be useful to pathologists include:
  - Laboratory accreditation process (eg, results from proficiency testing)
  - Maintenance of certification activities (eg, 360 degree evaluations)
  - Continuing medical education
  - Quality assurance and improvement activities (eg, peer review monitoring)
  - Proctoring of specific or all activities
  - Physician satisfaction survey results

Performance Feedback

1. Provide feedback in the form of reactions. Give details on why the observed behavior was good or needed improvement.
2. Conduct brief status meetings on a weekly or monthly basis to review how things are going.
3. Implement an open-door policy in which the employee can come to the supervisor for guidance and coaching any time it is needed.
4. Set up mentors for employees, either by a senior incumbent or by the supervisor.
5. Ask employees questions. When employees come for feedback or coaching, focus on “what questions”—what do you want to have happen, what are actions you can take?