Technical Consultant/Technical Supervisor Q&A

1. **Can a moderate complexity lab have multiple Technical Consultants?**

   Yes – as long as they are all qualified and the responsibilities are being met, there is no CLIA or COLA restriction on the number of TCs that can work with a lab. There should be a clear and written schedule or delineation of duties, so that all TCs working with a lab are clear on what responsibilities they are assigned.

2. **Is there a limit to the number of labs that a Technical Consultant can be the Technical Consultant for?**

   No. CLIA does not restrict the number of labs that a TC can work with. Many TCs have built successful businesses across multiple states. But, we recommend that any TC, who serves multiple labs, be aware of their own limitations as far as how many they can adequately keep up with the important responsibilities of the position. We sometimes see very good TCs who have spread themselves too thin to keep up with a large number of labs.

   Technology allows some of the oversight to be done remotely. However, a TC should schedule regular visits with each lab, so that they can keep a good handle on the lab's level of compliance to standards. Also, TCs should schedule regular meetings with the Lab Director, as this is a vital partnership.

3. **Can an RN serve as Technical Consultant?**

   If an RN meets the minimum qualifications of a TC, they can certainly fill this role. Typically RNs do not have the required Bachelor's degree in a Chemical, Biological, Physical, or Clinical Laboratory science, so we don't see RNs serving as TCs very often. Many RNs do very well at day-to-day oversight of lab testing in their facilities, and are very committed to the quality of lab services for their patients, but not many have the required minimum education qualifications for TC.

4. **I am a Cardiopulmonary Director. I am A Registered Respiratory Therapist with a Bachelor of Science Degree in Health Care Management with a blood gas lab. We do ph, co2, po2, bicarb, and carboxyhemoglobin. Will my degree qualify me for a technical supervisor or consultant or will my Lab director still need to sign off on my CVP's Delts and so on?**

   I am assuming that your lab is moderate complexity, in which case a Technical Consultant is required. The minimum education qualifications for a TC are a Bachelor's

degree in a Chemical, Biological, Physical, or Clinical Laboratory Science. The Health Care Management degree does not fall into one of these categories. While I am sure you are perfectly capable of many of the responsibilities of a TC, you cannot hold the CLIA position of TC. Your Lab Director may be qualified to fill the TC position, and it is acceptable to COLA if you work together on the responsibilities – but the Lab Director should do the final evaluations and approvals. Anything that the Lab Director delegates to you must be in writing.

5. **I have been an MLT since 1991; I am currently acting as the Technical Consultant in my Internal Medicine POL. Is this acceptable?**

   The minimum education requirements for Technical Consultant in a moderate complexity lab are a Bachelor's degree in a Chemical, Biological, Physical, or Clinical Laboratory Science. If you do not have at least the Bachelor's degree, then no, you would not be qualified to serve as the Technical Consultant. If your Lab Director is qualified to serve as TC (physician licensed in the state and a minimum of one year supervision of moderate complexity testing) then he/she can hold that role, and he/she could involve you in the responsibilities – but the LD would be responsible for the TC responsibilities. This does not mean that you can't be a vital contributor to the day-to-day operation and oversight of technical issues. You just can't hold the TC position.

6. **What if the Lab Director and the Lab Consultant is the same person. Who does their competencies at a POL?**

   The Lab Director is not required to undergo competency assessment for the positions they hold. The Lab Director will be evaluated during the on-site survey on how well they fulfill the responsibilities.

7. **What are the inspection expectations for a POL or Urgent?**

   POLs and Urgent Care labs have the same regulatory requirements as any other lab. An on-site survey is performed after initial enrollment (within 11 months) and biennially thereafter. As far as requirements for personnel, QC, QA, PT, record retention – these would be the same as for any other lab. If you have questions about specific requirements – please call COLA and we would be happy to help.

8. **Can the direct observation be done at a skills fair for point of care?**

   The requirement is for direct observation of routine patient testing – so this might be difficult to do at a skills fair. That said, I think skills fairs are a great idea and we would accept this as the direct observation element as long as they are able to demonstrate the procedure (including patient ID procedures) from start to finish using a volunteer as the patient.

9. **For toxicology QC, there aren't really trends or shift; we are looking for a target value with deviation of 10%. What do you recommend we do?**

   We realize that most mass spec labs don't use Levy Jennings graphs. However, if you use a target value of +/- 10% - you still should be able to evaluate cumulative QC. For example, if for 10 days in a row your value is 10% above the target – would you want to investigate and document any corrective action? Another example – if your values are +10% and then -10% and up and down and up and down, would you not want to try to find out why your precision isn't as good as you would want it to be? As Technical Supervisor, you are responsible for defining what needs to be done and when it needs to be done as a result of QC review. This doesn't look the same for every kind of lab, but you should have defined criteria that describe actions that should be taken and under what circumstances. The cumulative QC should still be reviewed.

10. **Does the TC have to be in the same state as the lab?**

    Not necessarily. Many TCs provide TC services to labs in other states. Many communications and reviews can be done from a remote location. Still, the TC should visit the lab on a regular basis so they have a good handle on what is happening at the lab. There is no regulatory requirement that mandates the frequency of visits. Be sure to pay attention to any state regulations that apply or that require supervisory licenses, such as in Florida.

11. **For a moderate Complexity lab, if the lab director is also the technical consultant/clinical consultant, can he designate someone in the department to perform competencies and he signs off on them?**

    The LD/TC/CC can delegate portions of the competency assessment to other persons in the lab, as long as that person is someone involved in the testing – for example it should not be an office manager that does not do any testing. Again the EVALUATION of competency must be done by someone meeting the minimum qualifications of the TC (in a moderate complexity lab) – so the LD/TC/CC MUST be the one to EVALUATE the information and make the final determination of competency or identify the need for further training.

    Just "signing off" on competency is not acceptable. But as long as the LD/TC/CC actually does the final evaluation then others can be involved in the required six elements. For example, the LD/TC/CC can delegate someone competent in the lab to gather up examples of problem solving, and to gather up PT reports. But, the LD/TC/CC should review everything and make the final assessment of competency.

12. **When changing a moderate complexity methodology, is an Implementation plan required by CLIA that would be signed by the LD, TC?**

    When introducing a new method, if the new method is FDA-approved, then it is required that accuracy, precision, reportable range, and reference range be verified. It is common for labs to have a written process for verifying these parameters. But, as long as the

parameters are verified and approved by the LD or designee, then a written procedure or implementation plan is not required. An implementation plan, with defined milestones for accomplishing the transition, including bringing up interfaces, etc., is a good idea for any lab, but not required by CLIA or COLA.

If the new method is non-FDA approved, then these as well as additional performance characteristics must be established.

It is important to remember that performance verification or establishment needs to be done by the lab's own staff.

13. **Is it acceptable for the TC to sign off on a point person's competency and make them an acceptable designee for the rest of the staff?**

    IF the "point person" meets the minimum qualifications of the TC (moderate complex lab) or meets the minimum qualifications of the TS or GS (high complex lab), then yes. BUT if the "point person" does not meet these minimum qualifications, then the TC can assign portions of the competency assessment, but the TC must be the one to do the evaluation of competency and indicate whether the person is competent or if more training is required. See #8 above.

14. **How do I evaluate a Clinical Consultant who does no testing?**

    You just need to evaluate whether the Clinical Consultant is meeting his/her regulatory responsibilities of the position. I am paraphrasing, but this includes making sure that the lab's reports include all information necessary for interpretation, and to be available to consult with the clients of the laboratory for issues such as test utilization or interpretation. We do have a modifiable template that you can use for this. It is included with the handouts.

15. **I am the only person working in the lab. We do not have a technical specialist. I am the lab supervisor and do all the testing. What should I do?**

    First, I need to know what your qualifications are and what complexity the lab is. It could be that if you have a physician Lab Director, that person may hold the official role of LD, TC, as well as Clinical Consultant. Without additional information it is difficult for me to answer your question. Please feel free to contact me directly: kathyn@cola.org. We can set-up a time to have a conversation.

16. **Competency is done initially- semi-annually. Is the first annual competency due 6-months after the 6-month competency or 12 months after?**

    The first annual competency is due 12 months after initial training, regardless of when the first semi-annual competency was done.

17. Can the duties of the TS be delegated?

The TC/TS can delegate responsibilities to others who meet the same minimum qualifications. A TC/TS cannot delegate everything to testing personnel who does not meet the TC/TS qualifications, but a TC/TS can certainly assign tasks to other competent testing personnel. The TC/TS has to demonstrate that THEY have fulfilled the responsibilities. Delegation of any portion of responsibilities (such as weekly QC review) should be in writing and signed by the LD and the TC/TS.

Let me give you an example. As we discussed during the webinar, it is the TC/TS responsibility to verify or establish performance characteristics for new methods. The TC/TS can certainly delegate precision studies, for example, to testing personnel. In fact, you really do want the people who will be doing the testing to participate in the validation studies. However, the TC/TS needs to be the one to review the data and approve, and make the determination if the studies are acceptable - if this has been delegated to the TC/TS by the Lab Director in writing.

18. If a lab director is also asking as a technical consultant who does their competency review?

A Lab Director is not required to undergo competency assessment for the positions that they hold. The Lab Director in this case will be evaluated for how well he/she fulfills the responsibilities of LD and TC – at the time of the survey.

19. I am a Quality Auditor, and new to COLA/CLIA regulations. Does every aspect need to be evaluated in staff competencies? For example, does staff need a competency performance for every piece of equipment they use, or can we do a representative sampling of equipment?

Testing personnel are required to have competency assessment for every test that they perform. So no, a sampling is not acceptable.

For panel tests, done on a single platform, it is acceptable to do a “core” competency for the platform – but you do need to include somewhere that they were evaluated for unique requirements for the individual tests. For example, if a Chemistry panel includes a potassium, you would want to include a review of the person’s competency to assess hemolysis and follow your procedures for handling hemolyzed specimens.

So you can streamline competency assessment for panels of tests on the same platform, but each individual test must be reflected in the assessment – with particular attention to any unique requirements for each test.

20. In a high complexity immunohematology lab, define "evaluating" testing personnel competency for the 1st year of competency testing. Does the TS have to actually sit down with the employee and observe the competency evaluation or can the TS review the competency records and sign-off.

Again, “sign off” is not a concept we like to endorse. It implies that someone else actually did the evaluation and all the TS did was “sign.”

But yes, the TS can review the competency records and make the determination of acceptable competency or decide if further training is needed.

21. Are there special qualifications or requirements for TS for Genetics labs performing pharmacogenomic and/or next generation sequencing testing?

First, you need to be clear on what CLIA specialty the testing falls under. If anything you are doing falls under what is considered Cytogenetics, COLA does not accredit this specialty – but there are specific TS requirements for Cytogenetics:

From CLIA:

“If the laboratory performs tests in the specialty of clinical cytogenetics, the individual functioning as the technical supervisor must—
(1)
(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and
(ii) Have 4 years of training or experience, or both, in genetics, 2 of which have been in clinical cytogenetics; or
(2)
(i) Hold an earned doctoral degree in a biological science, including biochemistry, or clinical laboratory science from an accredited institution; and
(ii) Have 4 years of training or experience, or both, in genetics, 2 of which have been in clinical cytogenetics.”

There are some pharmacogenomics tests that fall under the subspecialty of Toxicology, and do not involve traditional Cytogenetics (karyotyping). COLA does accredit for the specialty of Toxicology, which is a subspecialty under the specialty of Chemistry. The TS of high complexity Toxicology is required to have specific specialty experience.

Currently there are no additional specific CLIA regulations for the TS that supervises pharmacogenomics testing. But as this is a very specialized type of testing, it is certainly recommended that, in addition to the minimum education and experience requirements for TS in whatever specialty the testing falls under, the TS who supervises this type of testing have specific experience in pharmacogenomics.

It is very likely that COLA will implement additional experience requirements for the TS for this type of testing in the near future, as we did for the TS that supervises mass spectrometry.

22. Do we need to make a copy of a report that was used for a competency if I include the MRN for that particular patient?

It is certainly recommended that you include copies of the reports that were reviewed to satisfy this required element of competency assessment. But you are not absolutely required to include copies of reports – you can just indicate for example, an accession number of the report(s) reviewed.

23. Should each delegated task be written and signed off by the director?

Yes, when delegating tasks considered under laboratory director's responsibilities, the delegation should be in writing and signed by the laboratory director. One Lab Director responsibility is to have a written delegation of duties. Each lab should have a specific description of what each person is authorized to do, and this should be approved and signed by the Lab Director, even if some of the responsibilities delegated are those of the TC/TS.

24. Do you need to be licensed as a Technical Consultant in the State of Florida? Or would a Lab Supervisor licensed suffice?

There is no specific Florida state license for a technical consultant; a Florida Technologist license (TN) is sufficient. Therefore, if you have a Florida state Supervisor license (SU), you certainly quality as a technical consultant.

25. What if someone does not pass competency test?

Please keep in mind that there is no single competency test, rather competency is assessed through a series of direct observations, reporting activities, blind testing, and problem solving. If the person cannot not demonstrate competency, they must not be permitted to test until they do. The next step is to institute training or re-training, and then retest them for competency. You may opt to have their work reviewed for a time period. Once competency is demonstrated, they can perform testing. The training and competency assessments must be documented.

26. Can TC/ TS duties be delegated to the General Supervisor?

Yes, certain duties can be delegated, specifically following may be delegated:

- Resolving technical problems and ensuring remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications
- Ensuring patient test results are not reported until all corrective action has been taken and the test system is functioning properly;
- Providing orientation to all testing personnel;
- Annually evaluating and documenting the performance of all testing personnel.

The delegation of duties must be in writing.

27. Are private physician offices really expected to have a Technical Consultant on staff?

Yes, this is a CLIA required position for all moderate complex clinical laboratories. It does not matter whether the laboratory is a physician office laboratory, a reference laboratory or a hospital laboratory; or whether is it privately owned, or part of a corporation; or a government facility.

But the TC does not need to be on site at all times. They can be available for consultation via phone or email. Many small POLs contract with a TC, and typically the contract will spell out how often the TC is expected to visit and will also typically denote the CLIA responsibilities of the TC.

If a physician Lab Director has one year experience in the supervision and oversight of the non-waived testing performed, then he/she can qualify to serve as TC. While this is sometimes a successful model – we have seen that it is very difficult for a practicing physician to fulfill the responsibilities of a Technical Consultant.

28. Can a Medical Director sign-off on competencies?

Again, “sign off” often has connotation that we do not endorse. But yes, as long as the Lab Director meets the experience requirement for TC, then they can evaluate competency. So, medical directors can do this as long as they are qualified by virtue of their own training and experience. Usually, however, these assessments are handled by the technical supervisor or technical consultant, depending on the complexity of the laboratory.