



Technical Consultant / Technical Supervisor Responsibilities



Webinar For Clinical Laboratories January 25, 2016

Presenters

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Objectives

- Define the qualifications and responsibilities of the Technical Consultant and Technical Supervisor
- Provide examples that demonstrate the significance of these responsibilities in providing quality laboratory services
- Emphasize the importance of the relationship between the Technical Consultant / Technical Supervisor and the Lab Director

Required positions

	MODERATE COMPLEXITY	HIGH COMPLEXITY
Lab Director	X	X
Clinical Consultant	X	X
Technical Consultant	X	
Technical Supervisor		X
General Supervisor		X
Testing Personnel	X	X

Qualifications – Technical Consultant

- *MD, DO with their current medical license in the state of the lab's location and certified in Anatomic and /or Clinical Pathology, OR Equivalent Qualification.*
- *MD, DO, or DPM with current medical license in state of lab's location AND 1 year laboratory training /experience in non-waived testing, in the designated specialty /subspecialty of responsibility.*
- *PhD in Chemical, Physical, Biological science or Clinical Laboratory science AND 1 year training/experience in non-waived testing, in the designated specialty/subspecialty of responsibility.*

Qualifications – Technical Consultant

- ***Masters in Chemical , Physical, Biological or Clinical Laboratory science or Medical Technology AND 1 year laboratory training / experience in non-waived testing, in the designated specialty/subspecialty of responsibility.***
- ***Bachelors in Chemical, Physical, Biological or Clinical Laboratory science or medical technology AND 2 years laboratory training /experience in non-waived testing, in the designated specialty /subspecialty of responsibility.***

Qualifications – Technical Supervisor

Technical Supervisors in high complexity labs must have additional specialty or subspecialty specific qualifications.

Qualifications – Technical Supervisor

- *MD, DO with their current medical license in the state of the lab's location AND certified in anatomic and/or clinical pathology or equivalent qualification.*
- *MD, DO, DPM with their current medical license in the state of the lab's location AND 1 year training/experience in high complexity testing in the respective high complexity specialty.*

Qualifications – Technical Supervisor

- *PhD in Clinical Laboratory science, Chemical, Physical, Biological science AND 1 year training/experience in high complexity testing in the respective specialty.*
- *Masters in Medical Technology, Clinical Laboratory science, Chemical, Physical, or Biological science AND 2 years training/experience in high complexity testing in the respective specialty.*
- *Bachelors in Medical Technology, Chemical, Physical, or Biological science AND 4 years training/experience in high complexity testing in the respective specialty.*

Qualifications – Technical Supervisor

COLA staff will help evaluate degrees and transcripts if there are questions about what qualifies as a Chemical, Physical, or Biological science. Many courses of study are available now, that were not available when the CLIA regs were written.

Qualifications – Technical Supervisor

- *Some subspecialties require at least 6 months of specific experience in the subspecialty.*
 - *Example: Microbiology subspecialties:*
TS for high complexity Bacteriology -
BS Med Tech needs 4 years
high complexity Microbiology experience
– with at least 6 months experience with high complexity Bacteriology



Qualifications – Technical Supervisor

- ***Immunohematology***
 - ***Testing is Moderate complexity if performed for non-transfusion purposes – TC required***
 - ***Testing is High complexity if performed for transfusion purposes – TS required***
 - ***Unique TS qualifications:***
 - ***Board certified Pathologist OR***
 - ***Other licensed physician with 1 year training/experience in high complexity immunohematology***

Qualifications – Technical Supervisor

- *Mass Spectrometry*
 - *COLA has additional requirement for TS for mass spec testing:*
 - *Must meet the CLIA qualifications of the position AND*
 - *Minimum of 1 year experience in clinical mass spectrometry*

Some wear many hats...

It is not unusual for one individual to fulfill multiple roles.

For example, the physician may be the Lab Director, Clinical Consultant, and Technical Consultant for a moderately complex laboratory (if qualified).



Responsibilities – TC/TS

1. Selecting appropriate test methodologies for the test menu;
2. Verifying test procedures performed and establishing lab's performance criteria;
3. Enrollment in an approved PT program; monitoring participation.
4. Establishing a QC program appropriate for testing performed and establishing acceptable levels of analytical performance;

Responsibilities – TC/TS

5. Resolving technical problems and ensuring remedial actions are taken when test systems deviate from established performance specifications;
6. Ensuring that test results are not reported until all corrective actions have been taken and test system is functioning as expected;
7. Identifying training needs and ensuring that testing personnel receive necessary training and education;
8. Evaluating competency – (more on this subject later)

Responsibilities – TC/TS

Establishing a QC program appropriate for testing performed and establishing acceptable levels of analytical performance....

You should now be able to see the critical role of the TC/TS related to IQCP!

Responsibilities – TC/TS, compared to LD

Area of responsibility	Lab Director	TC/TS
Test selection	Ensure that methodologies selected have the capability of providing the quality of results required for patient care.	Selection of test methodology appropriate for the clinical use of the test results.
Performance specs	Ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics...	Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy...
Quality Control	Ensure that QC and QA programs are established and maintained to assure the quality...	Establishing a QC program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance....

Responsibilities – TC/TS, compared to LD

Area of responsibility	Lab Director	TC/TS
PT enrollment	Ensure that lab is enrolled in an HHS approved PT program for the testing performed..	Enrollment and participation in an HHS approved PT program commensurate with services offered.
Training	Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriated training for the type and complexity of the services offered...	Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the lab services performed.

Responsibilities – TC/TS, compared to LD

Delegation of duties and responsibilities should be specific for your lab and must be in writing.

The vital collaboration between LD and TC/TS

Let's demonstrate...



Does the Technical Supervisor/Technical Consultant adequately fulfill the responsibilities of the position?

Examples of Non-Compliance Scenarios

- **2016 PT enrollment does not include the new chemistry tests added when their Ortho Vitros 250 was replaced by the new chemistry instrument;**
- **No documentation of review of graded results for any PT events of 2015.**

Some of the lab staff have not been adequately trained on the new chemistry analyzer;

- **Staff has not had competency / performance evaluations since 2014.**

Does the Technical Supervisor/Technical Consultant adequately fulfill the responsibilities of the position?

Corrective Actions

- a) Required Proficiency Testing enrollment; performance, review of results; and corrective actions taken**
- b) Ensure that all relevant staff are adequately trained on new instrumentation and testing**
- c) Timely performance evaluations and competency assessments**

Does the Lab Director or qualified designee regularly review the quality control data with laboratory personnel?

The Lab Director is responsible to assure that QC is routinely reviewed to detect and correct potential problems that may impact the accuracy of patient results. This responsibility is often delegated to the TC/TS. The reviews should be initialed by the person reviewing them.

QC review

The QC review should assess the following for acceptability with laboratory policy:

- The number, type and frequency of QC performance;
- The acceptability of QC results;
- Any corrective actions taken for out of range results.

QC review

Scenario of non-compliance:

Two years worth of quality control have been printed and stored in several banker's boxes. Upon review by the surveyor, there is not one notation on the printouts that anyone has looked at them. Additionally, there are many areas of obvious trends and shifts that were not noted, nor was any corrective action found referring to the shifts/trends. And lastly, these were printed two days prior to the survey.

QC review

Corrective actions :

The Technical Consultant / Technical Supervisor should sign off that they reviewed the information on a monthly basis. Additionally there should be some documentation that shifts and trends noted were reviewed and corrective action was taken by the laboratory personnel. This should be done every 5-7 data points.

Procedures and verification studies

Non-Compliance Scenarios

- Many approved Laboratory Procedures lack important pre-analytic instructions;
- Written procedures have not been updated when test kits have been changed for the same tests;
- Performance verifications on new test systems have not been carried out as required

Procedures and verification studies

Corrective Actions

- Review all procedures to ensure that they address all important pre-analytic considerations; make sure that specimen collection staff are adequately trained. Make sure that the Lab Director has approved any necessary revisions.
- Ensure that all performance verifications are performed as required, on schedule, and involving the laboratory staff, not solely the manufacturer's technical representative.

Meaningful competency assessment






We can easily define competency, but evaluating competency in a meaningful way can be challenging.









Why the emphasis on competency?

- “Studies indicate that more education & training produce higher quality results.” Judy Yost, “CLIA Compliance, PT, and Quality Control: What’s New for 2012?” G2 Webinar 2012
- Competency confirms the effectiveness of training
- CLIA-defined Lab Director qualifications are stringent due to the overall responsibilities, but testing personnel qualifications are minimal, based upon complexity. Therefore, competence is critical.
- Errors may have impact on patients.

Assessing competency vs performance evaluations

	Team - work	Attendance and Punctuality	Productivity	Customer Service skills	Technical Competency
Personnel Performance Evaluation					

Some items that might be included on a personnel evaluation

<u>Direct Observation</u> – routine patient testing	
<u>Direct Observation</u> – instrument maintenance	
<u>Review of Records</u> - intermediate test records	
<u>Monitor Result Reporting</u>	
<u>Blind Sample Testing</u> - PT can satisfy this component	
<u>Evaluation of Problem Solving Skills</u>	

Required for competency assessment for testing personnel

Competency assessment

- WHO is required to undergo competency assessment?
 - Technical Consultant, Technical Supervisor
 - Clinical Consultant
 - General Supervisor
 - Testing Personnel

What about the LD?

The Laboratory Director is not required to have competency assessment – BUT is responsible for all CLIA defined responsibilities.

Competency assessment

- **WHO should evaluate competency?**
- CLIA gives this responsibility to the TC (moderate complexity) or TS (high complexity).
- Competency must be evaluated by qualified individuals (TC/TS/GS).
- Some components of the competency assessment can be delegated.

CLIA requirements for competency assessment

Six required elements of competency assessment

Competency assessment

- Two of the six required assessment activities involve Direct Observation:
 1. Direct observation of routine patient test performance;
 - 2. Direct observation of performance of instrument maintenance and function checks;

This can be documented with a detailed process oriented check list, per test or instrument.

Competency assessment

- Two of the six required assessment activities involve Review of Records:
- 3. Monitoring the recording and reporting of test results;
- 4. Review of intermediate test results, QC records, proficiency testing results, and preventive maintenance records;

Include with the competency documentation – records that were reviewed.

Competency assessment

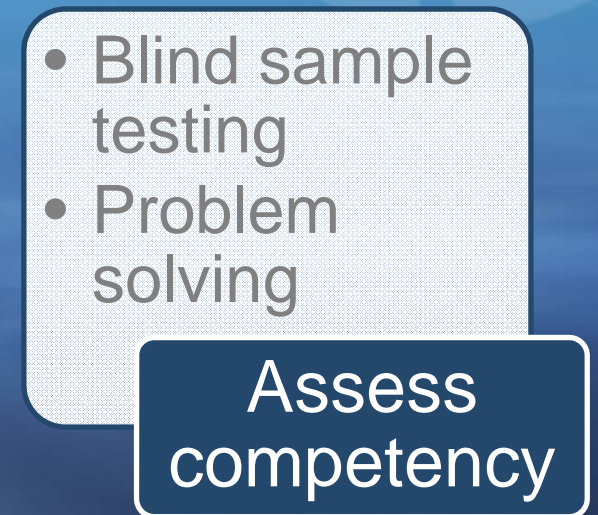
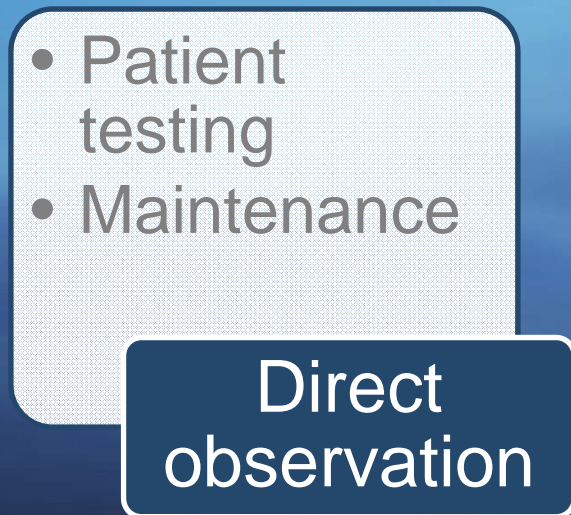
5. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples, or external proficiency testing samples;

Rotate the performance of PT samples among testing personnel!

- 6. Assessment of problem-solving skills .
 - Use problem logs, QC corrective action, complaint investigations, specimen rejection incidents...

Competency assessment

- *Don't waste paper*
- *Don't waste time*
- *Make it meaningful!*



Meaningful Competency Assessment

DOCUMENTATION should include:

- Direct observation – including list of the steps of the procedure or maintenance that were observed.
- Copy of the intermediate records that were reviewed.
- Copy or copies of test results that include necessary comments.
- Incident records, problem logs, or specimen rejection logs that demonstrate acceptable troubleshooting skills.
- Blind sample testing results with evaluation for acceptability. PT can satisfy this requirement.
- Final competency evaluation and conclusion.

Does your Technical Supervisor / Consultant periodically evaluate the performance and competency of all staff involved in testing as well as in technical supervisory and consultative roles.

Non-Compliance Scenario

- 1. General evaluations of work in the office are performed, but no review of specific technical competency occurs related to laboratory duties.**
- 2. Nursing staff are reviewed on their nursing competencies, but no evaluation occurs for the laboratory testing that they perform.**
- 3. Evaluations are performed verbally, but are not documented.**
- 4. Evaluations are not performed regularly; only immediately ahead of a COLA survey.**

Does your Technical Supervisor / Consultant periodically evaluate the performance and competency of all staff involved in testing as well as in technical supervisory and consultative roles.

Corrective actions

- **Bring competency assessments up to date for all staff, and build in calendar reminders for required competency assessments.**
- **The nursing competencies are expanded to include evaluations of their laboratory duties.**
- **All evaluations are documented and signed/dated when performed.**
- **Competency assessments are annually, except for the initial year of employment when semi-annual competency assessment is required.**

FAQ

Who should assess the competency of the Technical Consultant or Technical Supervisor?

FAQ

Does COLA have any customizable templates for competency assessment for all of the positions that require competency assessment?

FAQ

I am a nurse and in my POL my title is “Lab Supervisor.” How does this position relate to the Technical Consultant?

Have you any Questions?



How COLA Can Help

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