

# AABB Annual Meeting Education Program 2014

October 25-28, 2014 | Pennsylvania Convention Center | Philadelphia, PA



## Presentation Handouts

### (9123-QE) Competency Assessment: A Toolbox

October 25, 2014 ✧ 2:00 PM - 3:30 PM



Advancing Transfusion and  
Cellular Therapies Worldwide



## Event Faculty List

**Event Title:** (9123-QE) Competency Assessment: A Toolbox  
**Event Date:** October 25, 2014  
**Event Time:** 2:00 PM - 3:30 PM

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**Strategies, Tips and Tricks  
to Competency Assessment**  
Regina Castor, BS MT(ASCP)SBB<sup>cm</sup>  
Deb Futral, BS MT(ASCP)

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*I don't have time for  
this!!!*

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**CLIA elements**

- ▶ Element 1: Direct observation of performance
- ▶ Element 2: Monitoring recording and reporting of test results
- ▶ Element 3: Review of worksheets, QC records, PT results, PM records
- ▶ Element 4: Direct observation of instrument maintenance/function checks
- ▶ Element 5: Testing of previously analyzed specimens
- ▶ Element 6: Assessment of problem solving skills

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## Use existing training checklists

**Initial Training**

Technologist: \_\_\_\_\_ Hire Date: \_\_\_\_\_

Trainer: Initial and date each item as the procedure or task has been reviewed and demonstrated.  
 Trainee: Initial and date each item to attest: 1) Training has occurred on the item, 2) You are competent in understanding and completing the procedure/task  
 Competency Assessment: Trainer will initial and date once the trainee has been observed successfully completing the task according to the current procedure.

Task	Procedure #	Trainer	Trainee	Competency Assessment
ABO Typing (Forward and Reverse)	TS.001 rev 2.5			
Antibody Screens (Tube Method)	TS.004 rev 5.1			
Selecting special units for Tm	TS.010 rev 2.3			
Performing a patient history check	TS.012 rev 1.4			

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## Training/competency checklists

**Mobile Infirmiry**  
INFIRMARY HEALTH

EMPLOYEE ORIENTATION - BLOOD BANK/GENERALIST

Name: \_\_\_\_\_ DR \_\_\_\_\_

Procedure	Read	Date/Initial	Competent	Date/Initial
Procedure Manual				
Quality Manual				
Critical Values				
Alarms				

**Direct Observation**

Procedure	Observed/Read Date/Initial	Skill Verbalized Date/Initial	Demonstrated Date/Initial	Competent Date/Initial
Group/Rh Type				
Antibody Screen				
Panel				
Direct Coombs				

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### DIRECT OBSERVATION CHECKLIST

Employee Name: \_\_\_\_\_ Job Assignment: **BB-1 Galileo**

Step Observed:	Acceptable?		
	YES	NO	N/A
1. Wears lab coat, gloves and face shield when appropriate.			
2. Set up specimen preparation			
3. Set-up and performs preventative maintenance			
4. Performs visual interpretation of plate results and compares to instrument results			
5. Successfully performs procedure			
6. Successfully performs manual weak D procedure			

Employee Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Observer Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Supervisor Assessment:

- Employee demonstrates competency
- Minor deviations reviewed. Employee demonstrates competency. (Document corrective actions below).
- Remedial training required. Employee cannot perform test until retraining is complete. Review employee's previous work to see if patient results were affected.

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### Instrument maintenance

- ▶ Direct observation of performance of instrument maintenance and function checks
  - Which instruments?
  - Who does it?

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### Use QA schedules to determine who and what to observe

2013 Quality Assurance - Scheduled QC/Maintenance						
Party	Character W	Character A	Unit	Area	Origina	Debbie
Jan	6 Ton Audit	6 Ton Audit	Waterbath Monthly Cleaning	Ton Audit	TQA, Training Report, Procedures review, QIP review	dig them con
Feb	6 Ton Audit	6 Ton Audit	Lubricate Basket Assembly, 6 Ton Audit	6 Ton Audit	TQA, Training Report, Procedures review, QIP review	Conder QC
Mar	High/Low Temp	6 Ton Audit	dig them con	6 Ton Audit	TQA, Training Report, Procedures review, QIP review	Waterbath Monthly Cleaning
Apr	6 Ton Audit	6 Ton Audit	Waterbath Monthly Cleaning	6 Ton Audit	TQA, Training Report, Procedures review, QIP review	
May	Waterbath Monthly Cleaning	6 Ton Audit	Lubricate Basket Assembly	6 Ton Audit	TQA, Training Report, Procedures review, QIP review	Conder QC
June	Confer Weather Testing and documentation	6 Ton Audit	6 Ton Audit	6 Ton Audit	TQA, Training Report, Procedures review, QIP review	dig them con
July	6 Ton Audit	6 Ton Audit	Waterbath Monthly Cleaning	6 Ton Audit	TQA, Training Report, Procedures review, QIP review	dig them con
Aug	Waterbath Monthly Cleaning	6 Ton Audit	6 Ton Audit	6 Ton Audit	TQA, Training Report, Procedures review, QIP review	Lubricate Basket Assembly
Sept	6 Ton Audit	6 Ton Audit	High/Low Temp	6 Ton Audit	TQA, Training Report, Procedures review, QIP review	dig them con

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### Making sure it gets done

- ▶ Some facilities put the responsibility of completing the 6 elements each year on the individual employees
  - Takes pressure off of Manager
  - Builds accountability
  - Rare tasks
  - Educational

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### Who can assess?

- ▶ Someone who
  - Has been trained
  - Can determine competent vs non-competent behavior
  - Is motivated to do it right
  - Must meet CLIA requirements

**It Doesn't Always  
Have to Be the  
Supervisor!!**

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### Who to consider

- ▶ Secret Shoppers
- ▶ Lead Techs
- ▶ Techs trained to task
- ▶ Others

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### Just remember...

Those who assess competency must also have their competency assessed IF they perform critical tasks!

**And that includes the supervisor!!**

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## Look at tasks you already perform

- Direct observation of performance
  - **Monitoring recording and reporting of test results**
  - **Review of worksheets, QC records, PT results, PM records**
  - Direct observation of instrument maintenance/function checks
  - **Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples**
  - **Assessment of problem solving skills**
- Most Blood Banks and Transfusion centers have these items already imbedded in their Quality Program

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## Aren't you doing this already?!

- Include as part of the competency policy
- Include items already being reviewed:
  - Recording and reporting of test results (daily test review)
  - QC records
  - Preventive maintenance records
  - Worksheets
  - If you're reviewing antibody panels, isn't that a problem solving skill? Transfusion Reaction workups?
- Document these in terms of competency

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All Routine Tasks		2011 Blood Bank Competency Assessment Summary							CLIA Element
		1. Direct Observation of routine patient test performance							
		Tech 1	Tech 2	Tech3	Tech4	Tech5	Tech 6	Tech 7	
ABO/Rh and antibody screen		11/1/2011	11/1/2011	11/1/2011	11/1/2011	Sep-11	12/6/2011	12/23/2011	
Other									CLIA Element
Accession # of test reviewed		2. Monitoring, recording and reporting of test results							
		Tech 1	Tech 2	Tech3	Tech4	Tech5	Tech 6	Tech 7	
ABO/Rh Antibody Screen		0223IH9	0223IH11	0207IH16	0225:IH10	0206IH13	12/6/2011	0225:IH3	110
Compatibility Antigen Typing		0223IH9	0223IH11	0207IH16	0225:IH10	0206IH13	12/6/2011	0225:IH3	110
Antibody ID		2/26/11 0105IH3	6/30/11 081TIHT	1/18/11	2/25/11	0801:IH2	7/23/11	NA	NA
TRXN		0317:IH16		0228IH24					

Courtesy of Lea Tolzmann, Winter Haven Hospital, Winter Haven, FL

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### Previously analyzed specimens

- ▶ Patient/Donor samples
  - Unique Samples
  - Routine Samples
  - Variable results depending on storage and use
  - Less Cost
  - Large resource availability
    - Hematology
    - Chemistry
  - Document Results

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### Internally prepared samples

- ▶ “Doctored” patient/donor samples
  - Can you get enough sample for multiple techs?
  - Stability and reproducibility
  - Can be time consuming to prepare
  - Less Cost
  - Document results
  - ≠Proficiency products (more flexibility)

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### Externally prepared samples

- ▶ Available from some Blood Suppliers as a value added service
- ▶ Purchased tech competency products (as opposed to Lab Proficiency products)
  - Scalable
  - CEUs offered
  - Can be used for multiple techs
  - ≠Proficiency products

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### Limitations when using proficiency samples for competency testing

- ▶ Rotating Lab Proficiency surveys does not satisfy all 6 of the CLIA requirements
- ▶ Proficiency samples must be treated like routine patient/donor samples
- ▶ Samples cannot be shared until results are received

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### Documentation of proficiency testing as competency

Proficiency Test Performance 2011					
	Date/Survey	Date/Survey	Date/Survey	Date/Survey	Date/Survey
<b>John</b>	ELU-A	HGB-A	AUT-A	JC-B	
	2/12/11	3/24/11	8/21/11	9/1/11	
Satisfactory Performance?	S	S	S	S	
<b>Paul</b>	DAT-A	ELU-B			
	1/5/11	3/27/11			
Satisfactory Performance?	S	U*			
<b>George</b>	HGB-B	DAT-B	JC-B Ed Challenge		
	9/1/11	7/5/11	9/1/11		
Satisfactory Performance?	S	S	S		

Satisfactory Performance (S): Acceptable results obtained compared to intended response. Results were recorded in compliance with current procedures. Testing was completed in the appropriate time frame for both accuracy and time parameters.

Unsatisfactory Results:

Corrective Action:

Paul, ELU-B – Procedure re-assigned to tech through the Learning Management System. Tech repeated testing on sample upon receipt of expected results. See direct observation checklist in personnel file.

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### Assessment of problem solving skills

- ▶ Written test or quiz
- ▶ Case Studies
- ▶ Scenarios: What would you do if...?
- ▶ Staff narrative

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### Look at elements that can be grouped

- ▶ **May I combine for competency purposes, all tests performed simultaneously on the same testing platform?**
- ▶ As long as there are no unique aspects, problems or procedures associated with any test on the testing platform, all tests performed simultaneously on the same testing platform may be combined. However, any test with unique aspects, problems or procedures within the same testing platform should be assessed separately to ensure that staff maintain their competency to report test results promptly, accurately and proficiently.

*-From the CMS Guidance document "What Do I Need to do to Assess Personnel Competency"*

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### Unsuccessful result

- ▶ **Process for Remediation**
  - Actions to take
    - Removing employee from testing until competency is demonstrated
  - Documentation
  - Recurrence
  - Re-assessment
  - Determination
    - Completion at end of each assessment

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### Documentation

- ▶ **Trackable and Traceable**
  - Checklist not sufficient
  - Each assessment requirement must be documented
    - Direct observation checklists
    - Title and date of record review
    - Title, date, sample ID if using PT
    - Graded test/quiz
    - Assessor name(s) and dates
    - Employee name

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## Competency policies

- ▶ The Transfusion Service at\_\_\_\_\_ maintains processes for evaluating competence before independent performance of assigned activities and for evaluating continued competence at specific intervals by review of proficiency testing performance and error tracking reports.

VS.

- ▶ The Transfusion Service at\_\_\_\_\_ maintains processes for evaluating competence before independent performance of assigned activities and for evaluating continued competence at specific intervals by the use of:
  - Direct observation of performance
  - Monitoring recording and reporting of test results
  - Review of worksheets, QC records, PT results, PM records
  - Direct observation of instrument maintenance/function checks
  - Testing of previously analyzed specimens
  - Assessment of problem solving skills

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## For more information...

- ▶ CLIA website: [www.cms.gov/clia](http://www.cms.gov/clia)
- ▶ Regulations may be found at <http://www.cdc.gov/clia/regs/toc.aspx>

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 Blood Systems



**Role of the CLIA Lab Director/CLIA Positions**

Terri Poulin, MT(ASCP)SBB  
Robin M. Cusick, MD

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**Acknowledgements:**

- Kathy Mackie-Golec, BS, MT(ASCP)
- Gayle Geele, MT(ASCP)SBB
- Kathleen Hopping, BS, CQA(ASQ)



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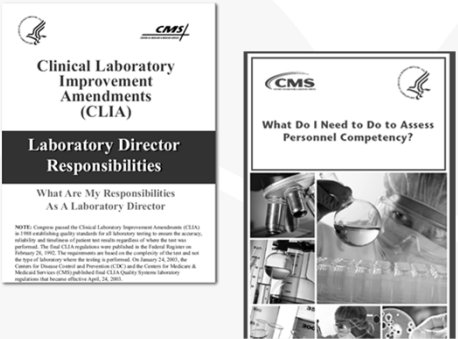
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### CLIA Lab Director

- Qualifications
  - Appropriately licensed and certified physician
  - Multiple other routes
  - CFR 493.1405 (moderate) and 493.1443 (high)
- Responsibilities and expectations of CMS:
  - To demonstrate active involvement in the lab's operations and availability to laboratory staff
  - Responsible for overall operation and administration of laboratory
  - Option to delegate, but retains ultimate responsibility for ensuring quality, operations, and regulatory compliance is achieved
  - A **key role** of being a CLIA LD is the responsibility to assess competency of delegated positions



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### Lab Directors should be involved!



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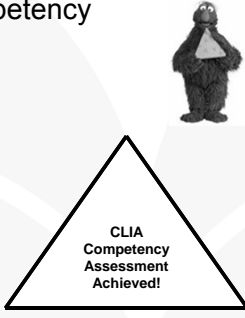
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### The 3 Parts of Competency Assessment

1. LD delegate responsibility to TS/TC, GS, and CC
2. LD assess competency of designees (TS/TC, GS, CC)
3. Designees can then assess competency of TP



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Terminology: CLIA Lab Positions for Testing

High Complexity	Moderate Complexity
Laboratory Director (LD)	Laboratory Director (LD)
Clinical Consultant (CC)	Clinical Consultant (CC)
Technical Supervisor (TS) General Supervisor (GS)	Technical Consultant (TC)
Testing Personnel (TP)	Testing Personnel (TP)

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Qualifications for High Complexity CLIA Designees

- Clinical Consultant
  - Must qualify as LD or be a physician with a state license
  - CFR 493.1417
- Technical Supervisor
  - MD or DO certified in clinical pathology
  - MD or DO with at least one year of lab training or experience in immunohematology
  - CFR 493.1449
- General Supervisor
  - Qualify as testing personnel under CFR 493.1489 and
  - Have at least 2 years of laboratory training or experience, or both, in high complexity testing



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**Q: I'm confused about all the different roles that Lab Directors (LD) can play.**

**Answer:**  
Lab Directors can serve as their own Technical Supervisors and Clinical Consultants and they can also delegate these positions to other MDs.

A LD can be the TS and CC, but also have other physicians as TS and CC to manage the daily workflow, sign PT if they are off-service, etc.



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High Complexity example:

- Big Bird is LD and TS and CC
- Big Bird also delegates TS and CC responsibilities to Cookie Monster.



CLIA LD and TS and CC



Designated as TS and CC

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Q: I'm the LD. Do I have to formally designate myself as TS and CC? Do I have to assess my own competency?

Answer: No and no. It is assumed that Lab Directors will serve as their own Technical Supervisors and Clinical Consultants. LDs should maintain requirements to qualify as CLIA LD.



CLIA LD and TS and CC

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First things first –

- Determine who the LD is and document it



Blood Systems Center Information

CLIA Position Responsibilities Laboratory Director/Clinical Consultant

Name: Big Bird Effective Date: 10/01/14

Responsibilities (SEE 482 & 483.145):

Responsible for the overall operation and administration of the laboratory, including the employment of personnel who are responsible to perform test procedures, and control and report test results promptly, accurately, and precisely and for ensuring compliance with applicable regulations.

The following responsibilities CANNOT be delegated:

If qualified, may perform the duties of the technical supervisor, technical consultant, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications.

Resumes responsibility for ensuring that all duties are properly performed if duties are reassigned to technical supervisor, technical consultant, clinical consultant, general supervisor, or testing personnel.

Accessible to the laboratory to provide onsite, telephone or electronic consultation to laboratory staff, as needed.

May direct no more than five laboratories.




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### Summary of Regulatory Responsibilities



<p><b>Clinical Consultant</b></p> <ul style="list-style-type: none"> <li>Available to provide clinical consultation</li> <li>Available to ensure that appropriate tests are ordered to meet the clinical expectations</li> <li>Ensure that reports of test results include pertinent information required for specific patient interpretation</li> <li>Ensure the consultation is available and communicated on QA testing issues</li> </ul>	<p><b>Technical Super./Consultant</b></p> <ul style="list-style-type: none"> <li>Available to provide consultation</li> <li>Select appropriate test methods</li> <li>Assure performance specifications are established</li> <li>Ensure enrollment and participation in PT</li> <li>Ensure QC program is in effect and adequate</li> <li>Resolve technical problems</li> <li>Identify training needs</li> <li>Evaluate competency of testing personnel</li> </ul>	<p><b>General Supervisor</b></p> <ul style="list-style-type: none"> <li>Accessible to testing personnel</li> <li>Provides day-to-day supervision</li> <li>Monitoring test analyses and specimen examinations</li> <li>Can be delegated to assess TP competency</li> <li>Other, as designated</li> </ul>
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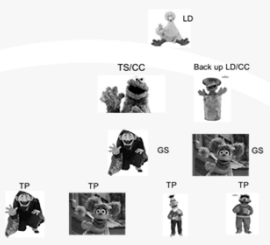
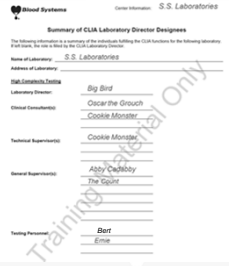
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### A summary of Designees can be helpful...

*Training Material Only*




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### Time to assess designee competency!

CLIA Laboratory Director determines competency of those individuals fulfilling the Personnel Categories at each site.

CC  
TS  
GS  
TC



This is a **key role** of being a CLIA LD.




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**Q: As the Lab Director, how do I actually assess and document the competency of my TS, CC, TC, and GS?**

- **Answer:** Actual process is not dictated – it is left up to LDs.
- LDs should be involved with the lab on a frequent and regular basis
- LDs should be familiar with and know their lab staff
- If an LD is unable to ensure competency of lab staff are assessed, may need to reassign LD duties




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**Example: S.S. Laboratories**

- *Big Bird (LD of SS Labs) is involved with the lab and familiar with the technologists in the lab.*
- *She participates in the hiring of the new night supervisor, the Count.*
  - *LD ensures that candidate's qualifications meet the job description and CLIA requirements for General Supervisor (GS)*
- **Initial assessment of competency:**
  - *To assess and document the Count's competency as a GS, Big Bird and the Count meet to review the list of what a CLIA GS is expected to do.*
  - *Big Bird has a conversation with the Count and asks questions about how the Count would handle different scenarios.*
  - *Big Bird documents the conversation and this serves as assessment of competency.*




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**Assessment of Designee Competency**

Blood Systems Center Information: S.S. Laboratories

CLIA Position Responsibilities Competency Determination

Name: The Count

CLIA Position: General Supervisor

Initial Competency Determination

The employee is competent to perform the position responsibilities for the position listed at the top of this form.

Employee Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Laboratory Director Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Annual Competency

The employee is competent to perform the position responsibilities.

The employee is competent to perform the position responsibilities.

- *After initial assessment, annual assessment of competency is required*
- *Perform these steps for each delegated position (TS, CC, TC, GS)*




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### One more time...who has to have Competency Assessment?



Answer: Anyone who performs critical tasks.

- Clinical Consultant
- Technical Supervisor
- Technical Consultant
- General Supervisor
- Persons performing testing on patient specimens
  - Testing personnel
  - Other CLIA positions who perform testing

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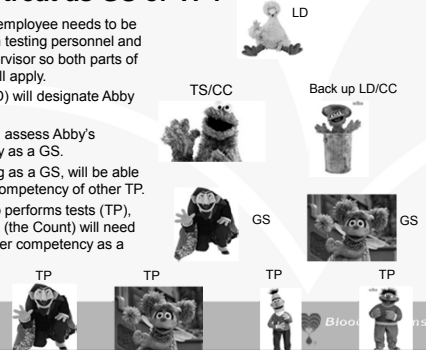
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### Q: My GS also performs testing. Do I need to treat as GS or TP?

Answer: This employee needs to be treated as both testing personnel and a general supervisor so both parts of this process will apply.

- Big Bird (LD) will designate Abby as GS
- Big Bird will assess Abby's competency as a GS.
- Abby, acting as a GS, will be able to assess competency of other TP.
- If Abby also performs tests (TP), another GS (the Count) will need to assess her competency as a TP.



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### Suggestions for LD Success



- ✓ Never be afraid to ask questions
- ✓ Know your staff
- ✓ Be involved in the hiring process -
  - ✓ LDs should be involved/informed in hiring personnel who may be CLIA designees - keep CLIA requirements in mind as well as job descriptions



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**CLIA designees (TS, TC, GS)  
can now assess the  
competency of testing  
personnel (TP)!**


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**Reminder of the ground rules...**

- Job Description ≠ CLIA Lab Positions
- Training ≠ Competency Assessment
- Personnel evaluations ≠ Competency assessment

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**The 3 Parts of Competency  
Assessment**

- ✓ LD delegate responsibility to TS/TC, GS, and CC
- ✓ LD assess competency of designees (TS/TC, GS, CC)
- ☐ CLIA designees can now assess the competency of TP




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### What Drives Competency Assessment for Laboratory Staff

**It's the right thing to do!!!!**

**It's required by regulation!**



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### 6 Core Competency Elements

- Direct observation of performance
- Direct observation of instrument maintenance/function checks
- Monitoring, recording, & reporting of test results
- Review of worksheets, QC records, PT results, PM records
- Testing of previously analyzed specimens
- Assessment of problem solving skills



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### Who Is Responsible for Performing Competency Assessment for TP?

- High complexity: TS performs competency assessments for TP
  - TS can delegate this, in writing, to a GS meeting CLIA qualifications
- Moderate complexity: TC performs competency assessments for TP
  - TC can delegate this to other personnel meeting CLIA TC qualifications



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**Q: How often is competency of testing personnel assessed?**

Answer:

- At least semiannually during the first year that the TP tests patient specimens
- At least annually thereafter *unless* test methodology or instrumentation changes
  - Prior to reporting patient test results, the individual's performance must be re-evaluated to include the use of the new test methodology or instrumentation



Blood Systems

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**Q: Do all six procedures of competency assessment need to be performed at the same time each year?**

Answer: No, competency assessment can be done throughout the entire year.

The laboratory may coordinate the competency assessment with its routine practices and procedures to minimize impact on workload.




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**Q: How can I keep track of all this???**

Answer: one way is to develop a Competency Workbook to manage the documentation and ensure compliance.



Blood Systems

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### Competency Workbooks



BSI developed competency workbooks to help assess and document the competency for all staff performing testing.

Annual Assessment for (Year) \_\_\_\_\_

Employee Name: \_\_\_\_\_ EIN: \_\_\_\_\_

Transfusion Services Manual, 3-14

Required (X)	Area	Related SOPs	Completed
	Specimen Handling		
	Equipment Maintenance/Quality Control		
	Equipment Maintenance – TANGO		
	Reagent Quality Control		
	ABO/RH		
	DAT		
	Antibody Detection		
	Antibody Identification		
	Antigen Typing		

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### Workbook approval

After testing personnel employee is determined competent, competency is documented and LD reviews.



**Blood Systems** Center Information

CLIA Competency Approval

Signatures below indicate completion of and acceptable performance on appropriate sections of the employee's Competency Assessment.

Time Frame \_\_\_\_\_

Employee Signature \_\_\_\_\_ Date \_\_\_\_\_

Supervisor Signature \_\_\_\_\_ Date \_\_\_\_\_

CLIA Laboratory Director Signature \_\_\_\_\_ Date \_\_\_\_\_

Documentation sent to LIS \_\_\_\_\_



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### Q: Where is all this documentation kept?



**Answer:** In the laboratory, but not with the training documentation.



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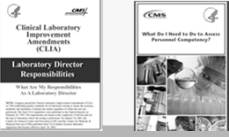
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### Summary of CLIA Toolbox Documents

- Documentation of LD
- Document of designees
  - Back up LD
  - TS/TC
  - CC
  - GS
  - Summary form can be helpful
- Documentation of Competency Assessment of designees
  - TS/TC
  - CC
  - GS
- Workbook or another collection to document testing personnel's demonstration of 6 core competencies
  - Signature page for LD review



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### The 3 Parts of Competency Assessment

- ✓ LD delegate responsibility to TS/TC, GS, and CC
- ✓ LD assess competency of designees (TS/TC, GS, CC)
- ✓ CLIA designees can now assess the competency of TP

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Thanks!



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**Competency Assessment: Is Your Program Competent?**

Holly Rapp, MT(ASCP)SBB, CQA(ASQ)CMQ/OE  
Judy Sullivan, MS, MT(ASCP)SBB, CQA(ASQ)

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**Objectives**

- \* Review and interpret the CMS regulations and expectations specific to CLIA Competency Assessment
- \* Describe common findings during inspections and assessments related to competency assessment

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**What Is Competency and Competency Assessment?**

- \* Competency is the ability of personnel to apply their skill, knowledge, and experience to perform their laboratory duties correctly.
- \* Competency assessment is used to ensure that the laboratory personnel are fulfilling their duties as required by federal regulation.

Centers for Medicare and Medicaid Services

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### CLIA Competency Assessment Key Requirement

493.1413(b)(8)(9) & 1451(b)(8)(9)

Technical Consultant/Supervisor Responsibilities

- \* Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently

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### Competency Elements

- \* Direct observation of performance
- \* Direct observation of instrument maintenance/function checks
- \* Monitoring recording and reporting of test results
- \* Review of worksheets, QC records, PT results, PM records
- \* Testing of previously analyzed specimens
- \* Assessment of problem solving skills

Competency assessment must include all six elements for all tests performed

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### Frequency

- \* At least semiannually during the first year the individual tests patient specimens
- \* At least annually thereafter unless test methodology or instrumentation changes
  - \* Prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation

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**CLIA Relates To Testing Personnel**

What about non-testing personnel?

**YES!!**

Do I need to assess competency?

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**AABB**

**STD 2.1.2 Training**

\* The blood bank or transfusion service shall have a process for identifying training needs and shall provide training for personnel performing critical tasks.

**Not Just Testing Personnel!**

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**AABB**

**STD 2.1.3 Competence**

\* Evaluations of competence shall be performed before independent performance of assigned activities and at specified intervals.

\* 2.1.3.1 Action shall be taken when competence has not been demonstrated

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### What is the difference?

- \* Testing Personnel
  - \* All routine tests
  - \* All CLIA elements MUST be used for evaluation
- \* Other Personnel
  - \* Facility-specified



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### Who Is Required to Have a Competency Assessment?

- \* Anyone who performs testing on patient specimens
  - \* Clinical Consultant
  - \* Technical Consultant
  - \* Technical Supervisor
  - \* General Supervisor

"Competency assessment based on their federal regulatory responsibilities"

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### Technical Supervisor for Immunochemistry

- \* MD or DO certified in clinical pathology
- \* MD or DO with at least one year of lab training or experience in immunochemistry

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### TC/TS Regulatory Responsibilities

- \* Available to provide consultation
- \* Select appropriate test methods
- \* Assure performance specifications are established
- \* Ensure enrollment and participation in PT
- \* Ensure QC program is in effect and adequate
- \* Resolve technical problems
- \* Identify training needs
- \* Evaluate competency of testing personnel

**Remember: applies to moderate AND high complexity testing!**

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### General Supervisor Responsibilities

- \* Accessible to testing personnel
- \* Provides day-to-day supervision
- \* Monitoring tests analyses and specimen examinations
- \* Delegated responsibilities
  - \* Remedial actions taken when deviations occur
  - \* Ensure test results not reported until CAPA has been performed
  - \* Provide orientation to testing personnel
  - \* Annually evaluate and document performance of testing personnel

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### Who Is Responsible for Performing Competency Assessment?

- \* Technical Consultant – moderate complexity testing
  - \* Can be performed by other personnel meeting TC qualifications
- \* Technical Supervisor – high complexity testing
  - \* Can be delegated, in writing, to a General Supervisor meeting qualifications as GS for high complexity testing

"Peer testing personnel who do not meet the regulatory qualifications of a TC, TS, or GS cannot be designated to perform competency assessments."

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### Qualifications

- \* Technical Consultant
  - \* Bachelor's degree in chemical, physical or biological science or medical technology AND
  - \* Have at least 2 years of laboratory training or experience, or both, in non-waived testing
- \* General Supervisor
  - \* Qualify as testing personnel under 42CFR493.1489(b)2 AND
  - \* Have at least 2 years of laboratory training or experience, or both, in high complexity testing

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### Do all six procedures of competency assessment need to be performed at the same time each year?

“No, competency assessment can be done throughout the entire year. The laboratory may coordinate the competency assessment with its routine practices and procedures to minimize impact on workload.”

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### Proficiency Testing and Competency

- \* PT performance may be used as part of competency
- \* PT is not sufficient to meet all six required elements

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**Danger, Danger, Will Robinson!!!**

**DO NOT** share PT samples with other staff until **AFTER** the results have been received from the PT provider

A cartoon robot with a square head, a small antenna, and a body with a rectangular panel. It has small arms and legs. Several lightning bolts are striking its head, and it has a jagged, lightning-like mouth.

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**What Are Assessors Finding?**

A black and white photograph of a man in a white shirt and tie, looking through a magnifying glass held up to his eye.

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**Common Findings**

- \* Lack of documentation of training separate from competence assessment
- \* Only direct observation documented
- \* Only a quiz distributed
- \* Not every individual tests an unknown specimen for each test yearly
- \* Not all tests assessed

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## Lessons to Learn

- \* Know the requirements
- \* Focus on tests and the six elements to assess competency to perform them
- \* Don't forget non-testing personnel
- \* Try to keep it simple

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## Thank you!!



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