Presentation Handouts

AABB Annual Meeting Education Program 2014



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

(9123-QE) Competency Assessment: A Toolbox

October 25, 2014 \diamondsuit 2:00 PM - 3:30 PM





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)SBBcm Deb Futral, BS MT(ASCP)



CLIA elements

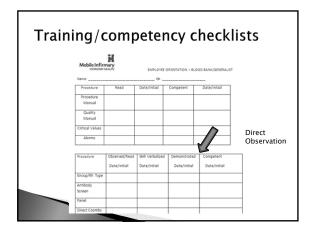
- Element 1: Direct observation of performance
- Element 2: Monitoring recording and reporting of test results
- Element 3: Review of worksheets, QC records, PT results, PM records
- Element 4: Direct observation of instrument maintenance/function checks
- Element 5: Testing of previously analyzed specimens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

Direct observation checklist

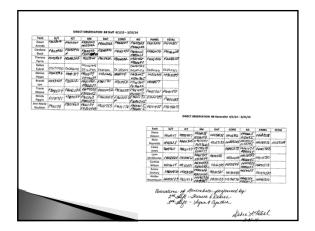
- ▶ Make a checklist from your SOP
 - Use at conclusion of training on that SOP
- Use for
 - 6 month/90-day competency assessment
 - · Annual competency assessment
- Good way to audit SOPs as you are creating the checklist

uditor		
nit #		
Transporter: Item Observed:		
ransporter presented blood order		
lood order contained 2 identifiers		
he proper unit was retrieved from the torage unit		
he tech verbally read off the following: a. Patient Name b. Date of Birth c. Medical Record Number d. Unit # e. Component type f. Special requirements g. Blood type of Component h. Blood Type of Component h. Blood Type of patient l. Compability status		

	9 114	umir	ng ci	าeckli
	Initial Training	3		
Technologist:	Hire D	ate:		
Competency Assesment: Trainer will in		trainee has been	observed successful	
Competency Assessment: Trainer will in completing the task according to the cu		trainee has been	n observed successful	Competency
		Trainer	n observed successful Trainee	
completing the task according to the cu	rrent procedure.			Competency
completing the task according to the cu	Procedure #			Competency
completing the task according to the cu Task ABO Typing (forward and Reverse)	Procedure # TS.001 rev 2.5			Competency



Employee ?	Name:	Job Assignment:	BB-1 C	alileo	
			Acce	ptable?	
Step Observ	red:		YES		N/A
		shield when appropriate.	-	-	-
2. Set up spe	ecimen preparation				
3. Set-up an	d performs preventati	ve maintenance			
4. Performs	visual interpretation o	f plate results and compares to			
instrument r					
	ılly performs procedu				
Successfu	illy performs manual v	weak D procedure			
			_		-
				_	\vdash
Employee S	Signature:		Date: _		_
Observer S	ignature:		Date: _		_
Supervisor A	Assessment:				
	Employee demonst	rates competency			
ñ		rates competency eviewed. Employee demonstrates (competence	. (Doc	ument
_	corrective actions b		competency	. ,500	um ent
		required. Employee cannot perform	n test until	retraini	nσ is
		employee's previous work to see it			



Tracer audits

- Effective at looking at a variety of documents, staff
- Can be Retrospective
- Can be Retrospective
 Following a unit being transfused back to time of collection, reagents used, QC, equipment used, results recording, etc.
 Can be forwarded looking
- Ex: following equipment from purchase to discontinuation
- Crossmatch sample collection through transfusion
 Donor collection through processing/labeling

Tracer audits can easily incorporate several elements of CLIA by looking at a variety of records

Blood Order
Consent
Physician • Proper Utilization?
Turn around Time (order to receipt)
Was the sample processed correctly
labeling
Equipment use
Reagent QC/Receipt
Blood Bank Results reporting
Time out process (NSPG #1)
Proper use of filter
Transfusion protocol
Nursing Transfusion Reaction reporting (if indicated)

Instrument maintenance

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

Use QA schedules to determine who and what to observe

	Patty	Christy W.	Christy A	Julia	Ann	Regina	Debbie
Jan		. 6 Txn Audits	6 Txn Audits	Waterbath Monthly Cleaning	Txn Audits	TQI, Treume Report, Procedure review, QIF review	dig therm corr
Date/mitiete							
Feb	RPM/Timer Callb	Lubricate Basket Assembly, 6 Txn Audits	6 Txn Audits/	dig therm corr.	Txin AuditsWaterbeth Monthly Cleaning	TQI, Trauma Report, Procedure review, QIF review	Cooler QC
Outerinities							
Mar	High/Low temps	6 ten audits	dig therm corr. 6 Txn Audits		Tan Audits	TQI, Trauma Report, Procedure review, QIF review	Waterbath Monthly Cleaning
Date/initials							
Apr	Timer Checks	6 kin audits, Waterbath monthly Cleaning	6 txn audits	dig therm corr.	Txn Audits	TOX, Trauma Report, Procedure review, QIF review	
Onte (mitials							
May	Waterbath Menthly Cleaning	RPM/Timer Calib, 6 Txn Audits	6 bin audits	Lubricate Basket Assembly	Txn Audits, dig therm /method correlation	TQI, Trauma Report, Procedure review, QIF review	QMS Backup aud
Date Initials							
June	Cell Washer Tubing contact biomed get documentation	6 Txn Audits	6 twn audits Data Verification	Waterbath Monthly Cleaning.	Txn Audits, High/Lo Temps- Helmors	TQI, Trauma Report, Procedure review, QIF review	dig therm corr.
Date(nitials							
July		6 two audits	Waterbeth Monthly Cleaning, 6 bin Audits		Tim Audits, EXM Verification	TQI, Trauma Report, Procedure review, QIF review	dig therm corr.
Date/initials							
Aug	Waterbath Monthly Cleaning	dig therm corr. 5 Txn Audits	6 Txn Audits	RPM/Timer Calib	Txn Audits, QMS Backup audit	TQI, Trauma Report, Procedure review, QIF review	Lubricate Basket Assembly
Date/initials							
Sept		6 ten audits	6 Txn Audits High% o Temps-All		Txn Audits, Waterbath Monthly Cleaning	TQI, Trauma Report, Procedure review, QIF review	dig therm corr.
Date-Initials							
						TQt, Trauma	

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

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!!

Who to consider

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

Just remember...

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

And that includes the supervisor!!

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

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

utine	2011	Riood	Bank C	.ompet	ency A	ssess	me
			Su	ımmar	V		CLI
-	1. Direct (Observation	of routine		,	nc	Elei
*		Tech 2					Tech
ABO/Rh and							
antibody	11/1/20	11/1/20	11/1/20	11/1/20		12/6/2	12/
screen	11	11	11	11	Sep-11	011	2
Other						CLIA	
						Eleme	
	Tech 1	Tech 2	Tech3	Tech4	Tech5	Tech 6 12/6/20	Tech
wed 🔼			ording and				Tarak
ABO/Rh	0223IH9	0223IH11	0207IH16	0225:IH10	02061H13	12/6/20	0225
						12/6/20	
Antibody							h
Antibody Screen	0223IH9	0223IH11	0207IH16	0225;IH10	0206IH13	11	
Screen						12/6/20	0225
			0207IH16 0207IH16				0225
Screen Compatibility	0223IH9 2/26/11	0223IH11 6/30/11	0207IH16 1/18/11	0225;IH10 2/25/11	0206IH13 7/23/11	12/6/20 11	0225
Screen Compatibility Antigen Typing	0223IH9 2/26/11	0223IH11	0207IH16 1/18/11	0225;IH10	0206IH13 7/23/11	12/6/20 11 NA	0225 0 NA
Screen Compatibility Antigen	0223IH9 2/26/11	0223IH11 6/30/11	0207IH16 1/18/11	0225;IH10 2/25/11	0206IH13 7/23/11	12/6/20 11 NA	0225; 0

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		I		
Process/Procedure/Task Antibody Identification Direct Observation	Expectation All E/V Techs In Selects and tests appropriate panel cells	Pass/Fai	I Comment	Evaluator
Monitoring Test Result	ck Panel worksheet review			
Direct Observation of Maintenance/Qi	ce Performs QC on all panels re Performs CAP or Blind sample			
Problem Solvin	All panel cells are positive including the auto control. What do you do next?			
Elution Direct Observation	Properly prepares sample for testing All E/V Techs			
	Selects antigen negative blood for patient			
Monitoring Test Result	with positive antigen s Records QC reactions correctly via Orders and confirms antigen testing			
Direct Observation of Maintenance/Qi	C Selects correct cell for positive QC Performs CAP or Blind sample			
Problem Solving	Reactivity demonstrates as mixed field. What could be one reason for this?			
Issuing Blood Components	All E/V Techs Nursing staff reads all the required			
	information from the pickup form AND BB staff enters the name and BBID# from the			
Direct Observation	BBID# on pickup form does not match the			
Problem Solving Transfusion Reactions	All E/V Techs			
Direct Observation Monitoring Test Result	n Performs visual inspection correctly is Enters patient Special Messages			
	Competency Assessment			
Name:	Year:			
	isanulan, martial multo, sedeladan in amfidiena sunas, austi ig senera marto, menterera martio, 65 martio, estad Stick ling endintality astiaming enditardament	grain		
Aree Assessed	Assessment Supervisor Assessment C tool 1 Competent 2 Minor deviation	omment		
Routine Senon Testing: Asourts, ICT, Cressmook, 047, Cord, Pool	1.//ejor devision	\dashv		
Routine Senan Testing: Addish, (CT. Cressmith), DAT, Cerd, Add Seron, Addign Senanting ABBO - peaks, asserption, elucion Quality Control		=		
50+0 testing/ 00/ maintenance Transtusion reaction Transcusic Priestotomy		\equiv		
Cuelty Control SO/O sessing Control SO/O sessing CO maintenance Translation needlon Translation Needlony Infection Control (P\$I)States Cuelty Assumed "Psistates exercises, evident predict, and been gliesed sensibles, notices predicts induction, returned analysis predicts		=		
asserves, entering precioe, unit being, blood administration, break-sien indications, returned artificials				
products Bood Product - Issue, Product Outside, Sectional Conformation, Transfer on Production, Emography Address				
Non	Assessment to			
	ect Observation with date of observation	n		
M=r	ord review with type- R= results, QC= o maintenance			
TP Test	t performance and documented PT per z – written or oral with date and % pas	formance	A=acceptable U=unacce	eptable
Q Q01				
		Date:		
LIA!	Medical Director bile Infirmary Medical Center – Transfusion Ser	Date:		
7/2014	one infirmary medical center - franciscon ser	VIDE PO BOI	12144 MODIN, AL 38804	
Elamont	F E -			
Element	ι 5.			
 Assessmer 	nt of test perform	ance	through te	sting
previously	analyzed specime	ens.	internal blir	ıd
testing sar	mples or external	profi	iciency testi	na
samples		•	.,	5

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

Internally prepared samples

- "Doctored" patient/donor samples
- · Can you get enough sample for multiple techs?
- · Stability and reproducibility
- $\,{}_{^{\circ}}$ Can be time consuming to prepare
- Less Cost
- Document results
- #Proficiency products (more flexibility)

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

Example of exterr	nally prep	ared
Damp Workshop Sample Curra Objective: Aller Sample	Damp workshop I	Anti-Fy(a)
6. Ambody identification if needed e. Autocomysi if needed	Unknown Sample 2	Anti-Fy(a) and anti-K
Accuracy recod the results on the worksheet	Unknown Sample 3	Anti-Fy(a) showing dosage *
The sectiogical results for this specimes will be documed on a webcast to be held: Supportions will be seen closer to the time of the webcast.		
ABO SM		
Acids Acid	disse of antigen. Psychological sociation in circumstance of a stage affects. "Read more about 1.". The Dulys significance causing memory of commission reservation countries and stage a	region with health of the control of
	Courtesy OneBloo	, Denise Gilbert, d

How can these products be used?

- ➤ They do not have to be treated in the same manner as routine testing (≠Lab Proficiency)

 Direct observation potential

 Can be used by staff who have not completed a "wet challenge"

 Can be ordered as needed when new staff are hired

 Can be used for initial competency assessment

 Can be ordered as needed when methods are changed
- Use as corrective action for Laboratory PT failures
- Can be used regardless of test methodology being used
- Use as corrective action for near-miss events, Root cause analysis, etc.

Proficiency samples

- ▶ May (should) be used to fulfill competency requirement
- All labs have
- Limited volume/stability
- Unknown results
- May not be available when competency assessment is needed
- CE credits may be available

May I use Proficiency Testing (PT) performance to assess competency? Yes, PT performance may be used as part of your competency assessment; however use of PT performance alone is not sufficient to meet all six required

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

Documentation of proficiency testing as competency

	Date/Survey	Date/Survey	Date/Survey	Date/Survey	Date/Survey
John	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	
Paul	DAT-A	ELU-B			
	1/5/11	3/27/11			
Satisfactory Performance?	s	U*			
George	HG8-8	DAT-B	JC-B Ed Challenge		
	9/1/11	7/5/11	9/1/11		
Satisfactory Performance?	S	S	S		

Satisfactory: Performance (5): Acceptable results obtained compared to intended response. Results were recorded in compliance with current procedures. Testing was completed in the appropriate time frame for <u>auto</u> ground time parameters.

Unsatisfactory Results

Corrective Action

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

Assessment of problem solving skills

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

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	1
Ms. Jennifer case This samples from 183-year-old female (Jennife) who was admired into the emergency more with abdominal transma from a car accident. The patient stand of the last been preparat twice and that necessive all blood transfers on many years up-	
accident. The patient stated she has been pregnant twice and has seceived a blood transfusion many years ago.	
ABO Rh Antibody Screening -A -B -D OCT A1 B I III T/5 Interpretation	
18 4+ 0 3+ 3+ 3+ 0 +w	
1AT 0 2-	
1. List the thing: that should be done next:	
Teles 15, 1353-37 C. Igg.	
C D E C C C C C C C C C C C C C C C C C	-
3 0 0 0 0 0 - 0 - 0 0 - 0 0 0 0 0 0	
3 0 0 0 0 - 0 0 0 - 0 - 0 - 0	
*Check cells worked on all negative AHG reactions.	
What is the most likely antibody?	
What cannot be ruled out using this panel?	
What should be done next?	
g. Blood type of Component g. Yes 🗆 No 🗆	1
h. Blood Type of patient h. Yes □ No □ i. Compatibility status i. Yes □ No □	
Comments:	
The transporter was an active participant and verified the information Yes No	
as it was called out	-
The Unit was issued in the LIS per SOP Yes No	
Temperature control device was activated Yes No What if"	
Temperature control device was applied to the unit correctly Yes No questions to	
The unit was placed in transport bag Vec No No Satisfy Problem	
The patient's information was not visible in the transport bag Yes No requirement	
Problem Solving:	
1) What would you do if there was a mismatch between the patient identifiers on the unit and the order? Answer: 2) What would you do if the order said "irradiated blood" and the tagged unit was not irradiated?	
Answer:	
What could result if a non-irradiated unit was issued? Answer:	
Supervisor Review: Date: Participant is fully trained and competent to perform task successfully: Yes No	
Follow-up Needed:	
	- -
What about rare tasks?	
What about rare tasks:	
▶ Problematic areas:	
 Therapeutic Phlebotomies 	
 Adsorptions/Elutions 	
 Antibody Titers 	
Others??	
	I

Look at elements that can be grouped

- May I combine for competency purposes, all tests performed simultaneously on the same testing platform?
- 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. proficiently.

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

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

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.

- 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 onsichests, Cercents, FT results, PM records

 Direct observation of instrument maintenance, function checks

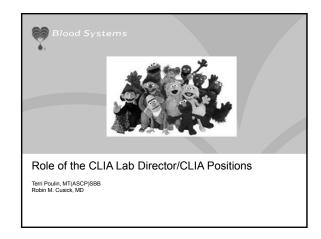
 Testing of periously analyzed specimens

 Assessment of problem solving skills

For more information...

- > CLIA website: www.cms.gov/clia
- Regulations may be found at http://wwwn.cdc.gov/clia/regs/toc.aspx

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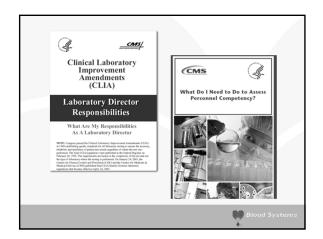


Acknowledgements:

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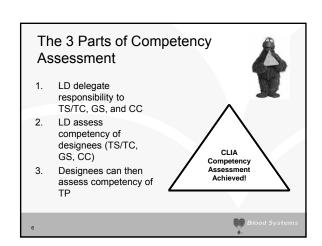


Blood Systems



CLIA Lab Director 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 Blood Systems





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)			
	Blood S	Systems		
alifications for High Compl	exity CLIA Designees			
Clinical Consultant	General Supervisor	Linder		
	General Supervisor Qualify as testing personnel CFR 493.1489 and			
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	General Supervisor Qualify as testing personnel			
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	General Supervisor Qualify as testing personnel CFR 493.1489 and Have at least 2 years of labstraining or experience, or both			
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	General Supervisor Qualify as testing personnel CFR 493.1489 and Have at least 2 years of labstraining or experience, or both			

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.



High Complexity example: • Big Bird is LD and TS and CC • Big Bird also delegates TS and CC responsibilities to Cookie Monster. CLIALD and TS and CC Designated as TS and CC

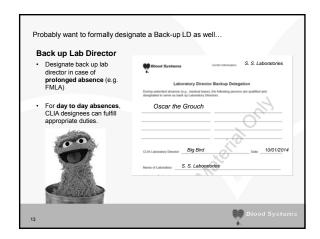
Q: I'm the LD. Do I have to formally designate myself as TS and CC? Do I have to assess my own competency?

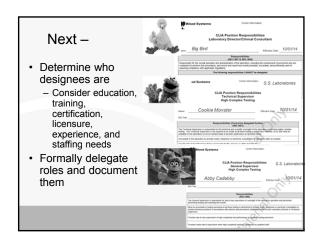
Answer: No and no. It is assumed that Lab Directors will serve as their own Technical Supervisors and Clinical Consultants.

LDs should maintain requirements to qualify as CLIA LD.

CLIA LD and TS and CC

First thir	ngs first –		
Determine v LD is and document it	•		400
	Blood Systems	Center Information:	- 11
	Υ.		
		Position Responsibilities Director/Clinical Consultant	
	Name Big Bird	Effective Date	10/01/14
		Responsibilities (493,1407 & 493,1445)	
	Responsible for the overall operation and admini competent to perform test procedures, and reco- assuring compliance with applicable regulations.	instration of the laboratory, including the employment of rd and report test results promptly, accurately, and prof	personnel who are locestly and for
	The following	g responsibilities CANNOT be delegated	
	If qualified, may perform the duties of the technic and testing personnel, or delegate these respons	cal supervisor, technical consultant, clinical consultant' sibilities to personnel meeting the qualifications.	, general supervisor,
	Remains responsible for ensuring that all duties technical consultant, clinical consultant, general	are properly performed if duties are reapportioned to le supervisor, or lesting personnel.	echnical supervisor,
	Accessible to the laboratory to provide onsite, te	riephone or electronic consultation to laboratory staff, a	s needed.
	May direct no more than five laboratories.		
			Blood Systems
			Y





Q: What does delegation of tasks to these individuals imply? Answer: It implies that you, as the LD, have confidence in these individuals' abilities to perform their regulatory responsibilities, including the ability to assess competency of testing personnel.

Summary of Regulatory Responsibilities



Clinical Consultant

- Inical Consultant
 Available to provide
 clinical consultation
 Available to ensure that
 appropriate tests are
 ordered to meet the
 clinical expectations
- Ensure that reports of test results include pertinent information required for specific patient interpretation
- Ensure the consultation is available and communicated on QA testing issues

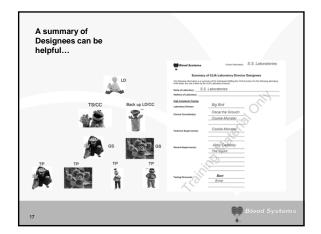
Technical Super./Consultant

• 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

- General Supervisor Accessible to testing
- personnel Provides day-to-
- day supervision Monitoring test analyses and specimen examinations
- Can be delegated to assess TP
- competency Other, as designated





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.



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



...





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 the
 - 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.

Assessment of Designee Competency



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



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Blood System

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



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
- 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.









Back up LD/CC



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





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

Reminder of the ground rules...



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

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



What Drives Competency Assessment for Laboratory Staff

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

It's required by regulation!





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



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



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





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.

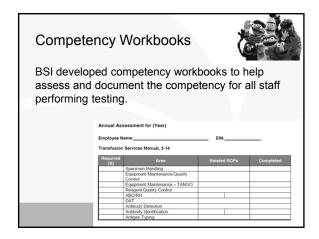


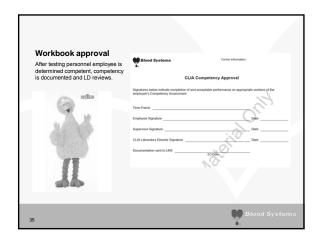
Q: How can I keep track of all this???

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



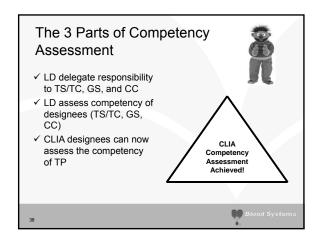




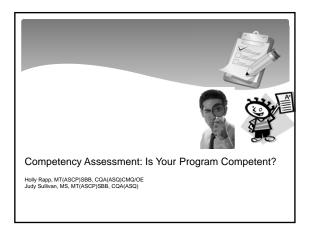


Q: Where is all this documentation kept? Answer: In the laboratory, but not with the training documentation.

Summary of CLIA Toolbox Documents Documentation of LD Document of designees Back up LD TS/TC CC GS Summary form can be helpful Output Tagener received in Abstraction Tagener received in the State of the







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

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

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

Competency Elements

- * Direct observation of
- 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

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

What about non-testing personnel? What about non-testing personnel? Do I need to assess competency?	
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!	
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	

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 Immunohematology

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

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!

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

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
 - $\ast\,$ 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."

	n

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

Danger, Danger, Will Robinson!!!

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



What Are Assessors Finding?



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

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!!

