



COLLEGE of AMERICAN
PATHOLOGISTS

2016 Focus on Compliance

**Organization of Personnel Education,
Training and Competency Records**

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Disclosure

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Today's Presenter



Mary Reznicek, MD, FCAP

Dr. Mary Reznicek has been the Pathology Director at ACL Wisconsin Central Laboratory for 20 years. She received her MD from University of Texas Health Science Center at San Antonio with residency and fellowships in Cytology and Surgical Pathology at University of Iowa. At CAP, she is currently a member of the Inspection Process Committee, and Regional Commissioner, Lab Accreditation Program, North Central USA. Dr. Reznicek has many years of leading inspection teams for the CAP Accreditation Program and a vast experience reviewing laboratory data and laboratory best practices.

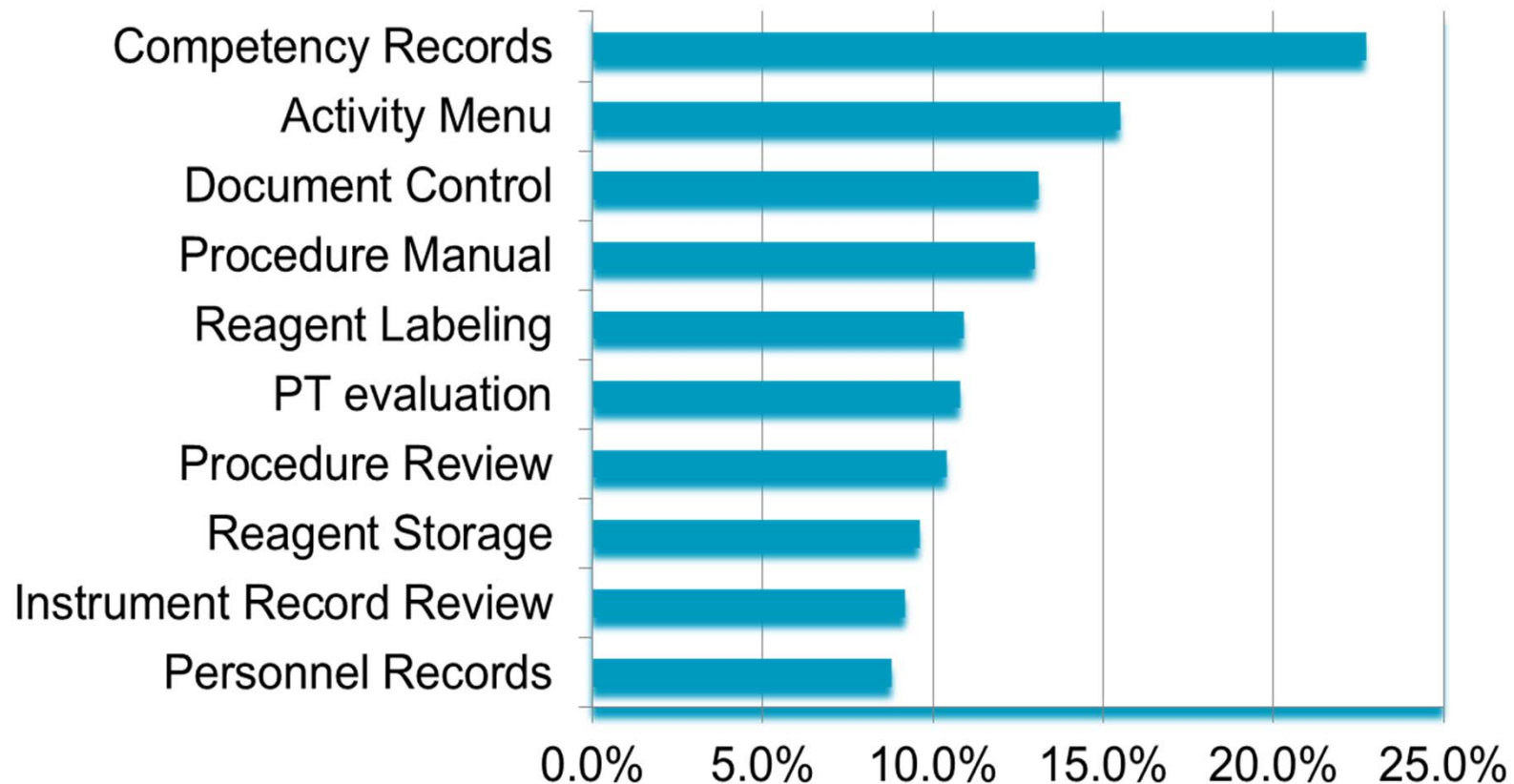
Objectives

- **Identify Laboratory General Checklist requirements that address personnel records**
- **Provide examples that show compliance with the Laboratory General Checklist requirements for personnel records**
- **Address the organization of personnel records**

Most Commonly Cited Deficiencies



Most Commonly Cited Deficiencies



Director Responsibility - Personnel

TLC.11300

The laboratory director ensures sufficient number of personnel with appropriate educational qualifications, documented training and experience, and adequate competency to meet the needs of the laboratory.

Key points —

- US laboratory personnel must meet personnel requirements of CLIA
- DoD laboratory personnel must comply with Clinical Laboratory Improvement Program Procedures
- VA laboratory personnel must comply with Veterans Health Administration Handbook
- Non-US laboratory personnel requirements must be defined and met



Director Responsibility – Delegation of Functions

TLC.11425

Delegation of the laboratory director's functions or responsibilities is in writing.

Key points —

- Laboratory director must ensure that all persons performing delegated functions are qualified to do so and that the delegated functions are properly carried out
- Delegated responsibilities and duties must be defined in writing

Personnel Records

GEN.54400

Personnel files are maintained on all current technical personnel and personnel records include the following:

Key elements —

- For nonwaived testing personnel, copy of academic **diploma or transcript**
- Laboratory personnel **license, if required** by state, province, or country
- Summary of **training and experience**
- **Certification, if required** by state or employer
- **Description of current duties and responsibilities** as specified by the laboratory director (procedures performed, whether supervision is required, etc.)
- Records of **continuing education**
- Records of **radiation** exposure where applicable
- Work-related **incident and/or accident** records
- Dates of **employment**



Personnel Records (cont.)

GEN.54400

- **DOD and VA laboratories may use CAP accepted credentialing services. The laboratory must be able to provide records of employee qualifications for all testing personnel on the day of inspection. These laboratories are not under the authority of the Centers for Medicare and Medicaid Services (CMS).**
- **Credentials for all personnel trained outside of the US must be reviewed and documented to ensure that their training is equivalent to CLIA requirements. Equivalency evaluations should be performed by a nationally recognized organization.**



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Continuing Education Records

GEN.54200

There is a functional continuing laboratory education program adequate to meet the needs of all personnel.

TLC.11200

The laboratory director ensures provision of educational programs, strategic planning, and research and development appropriate to the needs of the laboratory and institution.



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Maintaining Personnel Record Examples

Technical Personnel Records Checklist	
Employee Name	
Dates of Employment	
Date of Hire	Date of Termination
☐ Certification and/or Licensure:	
▪ Employee Degree (Transcripts or Diploma)	
▪ Certification or Registration (Board of Registry) (if applicable)	
▪ Current State License (if applicable)	
☐ Job Description	
▪ Procedures authorized to perform (waived, moderate, high complexity)	
▪ Supervision required: Process specimens; Perform testing; Result reporting	
▪ Supervisor/Director review required to report patient results	
☐ Summary of Training and Experience:	
▪ Resume	
▪ Initial Training	
▪ Competency Assessment – Initial 6 month; annual	
☐ Continuing Education	
☐ Radiation Exposure Monitoring (where applicable)	
☐ Visual color discrimination testing	
☐ Work-related Incidents and/or Accident Reports	

Maintaining Personnel Records (cont.)

Employee Name	Date of Hire	Job Description	License	Diploma/ Transcript	Application/ Resume	CEU	Initial Training	Six month Assessment	Annual Assessment	Annual Assessment

Personnel Folder Organization Example

Six Part Folder Tabs (can be placed at each tab or coversheet for folder)

Part 1 Demographics (maintain for 2 years after end of employment)

- ☐ Date of Hire
- ☐ Job Description
- ☐ Application/ Resume

Part 2 Regulatory (items in this section must be checked annually)

- ☐ License
- ☐ Certification
- ☐ CPR
- ☐ Radiation

Part 3 Performance (items in this section must be maintained per HR requirements)

- ☐ Annual Performance Evaluation
- ☐ Commendations
- ☐ Write Ups

Part 4 Competency (items in this section are maintained according to CAP requirements)

- ☐ Initial Training
- ☐ Six Month Assessment
- ☐ Annual Assessments

Part 5 Education (items in this section must be maintained for 2 years after end of employment)

- ☐ Degree/ Diploma/ Transcript
- ☐ CEU

Part 6 Miscellaneous

- ☐ Visual Discrimination
- ☐ Hepatitis Vaccine
- ☐ Annual TB
- ☐ Annual Safety

Maintaining Diploma/Transcript Records

Name of Laboratory:					
Employee name:			Date of employment:		
<div style="display: flex; justify-content: space-between; align-items: center;"> <div>_____</div> <div>attended/graduated</div> <div>_____</div> </div> <div style="display: flex; justify-content: space-between; font-size: small; margin-top: 5px;"> <div>Name</div> <div>Name of school</div> </div>					
Date(s) attended:					
List the dates and people (with their position/title) contacted and the efforts made to obtain a copy of this employee's diploma or transcript:					
Date	Name	Position/Title	Date	Name	Position/Title
Comments:					
<p>As the CAP Laboratory Director, I attest that _____ was trained and is fully competent to perform the above tests. This determination is based on my review of the employee's current competency assessment records, education and work history.</p>					
Signature:			Date:		
<p>Note: This form may only be used after efforts to obtain copies of the diploma or transcripts are documented.</p>					

Training vs. Competency

Training

- Occurs **before** patient testing begins
- Usually once unless employee fails successful demonstration of skill to trainer and **retraining** required
- **Does not require** use of six competency assessment elements

Competency

- Occurs **after** independent patient testing begins
- **Does require** use of six competency assessment elements for non-waived testing

Initial Training

GEN.55450

There are records that all staff have satisfactorily completed initial training on all instruments/methods applicable to their designated job.

Key skills – where applicable

- Specimen collection, including patient preparation, labeling, handling, preservation, processing, transportation, and storage of specimens, as applicable
- Implementation of all laboratory procedures
- Performance of each test method and for proper instrument use
- Preventive maintenance, troubleshooting and calibration procedure for each test performed
- Working knowledge of reagent stability and storage
- Implementation of quality control policies and procedures
- Awareness of factors that influence test results
- Assessment and verification of the validity of patient results, including the performance of QC prior to reporting patient results



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Initial Training

Attestation of Initial Training

Name of Laboratory:

Employee name:

Date of employment:

List all tests/platforms that employee has been trained and deemed competent to perform:

Test/Platform	Test/Platform

Some tests or duties may be performed but require supervision. List any tests/platforms that require supervision and specify whether direct or indirect supervision is required:

Test/Platform	Supervision	Test/Platform	Supervision

Comments:

As the CAP Laboratory Director, I attest that _____ was trained and is fully competent to perform the above tests. This determination is based on my review of the employee's current competency assessment records, education and work history.

Signature:

Date:

Note: this form should not be used in lieu of original training documents. This form may only be used if the original training documents are lost and appropriate attempts have been made to locate the original documents. If the original documents are available, they must be retained in the employee's file for the duration of their employment + 2 years.



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Competency Assessment of Testing Personnel

GEN.55500

Key Points -

- Competency at the required **Frequency**
- Competency using all **Six** applicable competency assessment elements
- Each **Test System**
- Competency using **Qualified Personnel**



Competency Assessment of Testing Personnel

GEN.55500

Frequency of Competency Assessment

- **For Waived testing:**

Competency assessment must be performed at least annually (semiannual assessment not required)

- **For Nonwaived testing:**

During the first year of an individual's duties, competency must be assessed at least semiannually

After an individual has performed his/her duties for one year, competency must be assessed at least annually

Competency assessment must include all six elements described below for each individual on each test system during each assessment period, unless an element is not applicable to the test system



Frequency of Competency Examples

Newly Hired	January 10, 2015
Completed non-waived training	February 5, 2015
First semi-annual Competency Assessment	August 5, 2015
Second semi-annual Competency Assessment	February 5, 2015
Annual Competency Assessment	February 5, 2016

Hired	January 10, 2015
Completed waived training	January 25, 2015
Annual Competency Assessment	January 25, 2016

Implemented new non-waived Instrument/Method	January 5, 2015
Completed training	January 25, 2015
New Test System added to Testing personnel's Competency and assessed when personnel's annual Competency Assessment is due	



Competency Assessment of Testing Personnel

GEN.55500

Elements of competency assessment include but are not limited to:

1. **Direct observations** of routine patient test performance, including, as applicable, patient identification and preparation; and specimen collection, handling, processing and testing
2. **Monitoring** the recording and reporting of test results, including, as applicable, reporting critical results
3. **Review** of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records
4. **Direct observation** of performance of instrument maintenance and function checks
5. **Assessment of test performance** through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and
6. Evaluation of **problem-solving** skills



Competency Assessment of Testing Personnel

GEN.55500

Test Systems

Definition —

- The process that includes **pre-analytic, analytic, and post analytic** steps used to produce a test result or set of results.
- May be manual, automated, multi-channel or single-use, and can include reagent components, equipment or instruments required to produce results.
- May encompass multiple identical analyzers or devices.



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Test System Example

Activity Menu:

- Hemoglobin, platelet count, RBC count, WBC count, hematocrit, WBC differential automated (Hematology analyzer)
- WBC differential manual
- PT, PTT, INR, D-Dimer (Coagulation Analyzer)
- Urinalysis dipstick automated
- Urine Microscopic
- Manual reticulocyte
- ESR, automated, non-waived
- Body fluid cell count, manual
- RSV non-waived,
- Strep A rapid antigen, waived



Competency Assessment

Semi-Annual/ Annual

Employee Name:											
Date of Hire:											
Period of Evaluation:											
Evaluator(s):											
Elements: 1. Direct observations of routine patient test performance, including, as applicable, patient identification and preparation; and specimen collection, handling, processing and testing 2. Monitoring the recording and reporting of test results, including, as applicable, reporting critical results 3. Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records 4. Direct observation of performance of instrument maintenance and function checks 5. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples 6. Evaluation of problem-solving skills											
		Hem Analyzer	Hem Diffs	Coag Analyzer	UA Analyzer	UA Microscopy	ESR	RETIC	BF	Kits(non-waived)	Kits(waived)
Elements	Specify Instrument / Assay										
	1 Patient ID/Prep										
	1 Specimen Collection										
	1 Handling/Processing										
	1 Testing										
	2 Reporting Criticals										
	2 Reporting Normals										
	3 Review worksheets										
	3 Review QC										
	3 Review PT results										
	3 Review PM records										
	4 Maintenance										
	5 Proficiency Testing										
	5 Blind Samples										
	6 Problem Solving										
Comments											
I have had an opportunity to review and ask questions about policies and procedures related to equipment and testing above.											
Employee Signature _____ Date _____											
Based upon successful completion of this competency assessment, this employee is deemed to be competent to perform patient testing unsupervised.											
Manager Signature _____ Date _____											
This employee needs additional training and is restricted from performing patient testing unsupervised. Action Plan and timeline for followup are listed below.											

After followup on issues related above, I feel confident in my ability to perform patient testing unsupervised.											
Employee Signature _____ Date _____											
Manager Signature _____ Date _____											



Microsoft Excel
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Example of Defined Test Systems

ANNUAL/SEMI-ANNUAL COMPETENCY ASSESSMENT



Microsoft Excel
Worksheet

Employee Name: _____

Date of Hire: _____

Period of Evaluation: _____

- 1 Direct observation of routine patient test performance including, as applicable, patient identification and preparation, handling and processing.
- 2 Monitoring the recording and reporting test results, including, as applicable, reporting critical results.
- 3 Review of intermediate test results or worksheet, quality control records, proficiency test resulting and preventive maintenance.
- 4 Direct observation of performance of instrument maintenance and function checks.
- 5 Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.
- 6 Evaluation of problem solving skills.

BLIND ABSC	#
BLIND DAT	#
BLIND FMH	#
BLIND SICKLE	#

		TUBE TEST							GEL TEST INDIRECT		GEL TEST DIRECT	KITS		
	Specify Instrument / Assay	ABORH	ABSC/ABID	ISXM	AHG XM	AG TYPE	DAT (IGG)	DAT(C3)	ABSC/ABID	AHG XM	DAT	FMH	SICKLE	ELUTION
1	Specimen Processing													
1	Patient ID accuracy													
1	Patient Testing													
2	Result Entry													
2	Reporting Criticals/Delays	N/A	N/A	N/A	N/A	N/A	N/A	N/A				N/A	N/A	N/A
3	Review Intermediate results/Worksheets	N/A		N/A	N/A	N/A	N/A	N/A		N/A	N/A	N/A	N/A	
3	Review QC									N/A				
3	Review Patient Results													
3	Review PM records	e)		b)		N/A	c)	c)	a)		d)	N/A	N/A	
4	Direct Observation of Maintenance	e)		b)		N/A	c)	c)	N/A	c)	d)	N/A	N/A	
5	Proficiency Testing or Blind Samples									c)				
6	Problem Solving													
	Comments													

a) daily temps; b) saline bottles; c) cell washer; d) MTS weekly, e)serofuge qc

- S Satisfactory - Requires minimal supervision with no more than 10% prompting and minimal oversight in less than the time scheduled.
N Needs Improvement - Needs additional training prior to working alone.

I have read and understand the standard operation of procedures for the tests listed above, and I had an opportunity to review and ask questions about policies and procedures related to equipment and testing above.

Date:	Employee Signature:	Date:	Evaluator Signature:
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Based upon successful completion of their competency assessment, the employee is deemed to be competent to perform patient testing unsupervised.

Date:	Technical Coordinator Signature:	Date:	Blood Bank Manager Signature:
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Competency Assessment of Testing Personnel

GEN.55500

The laboratory director must ensure that the individuals performing competency assessments are qualified through education and experience to meet the defined regulatory requirements associated with the complexity of testing.

Key points —

- Testing personnel performing **high complexity** testing must be assessed by the section director, or individual **meeting general supervisor requirements** for high complexity testing if **delegated** in writing by the section director
- Testing personnel performing **moderate complexity** testing, must be assessed by an individual **meeting the qualifications of a technical consultant** for moderate complexity testing



General Supervisor Qualifications

GEN.53600

Supervisors/general supervisors meet defined qualifications and fulfill expected responsibilities.

- **Must possess: Bachelor's degree in a chemical, physical, biological or clinical laboratory science or medical technology with at least one year experience with high complexity testing, or Associate degree in a laboratory science or medical technology program with at least two years experience with high complexity testing, or have previously qualified or could have qualified as a general supervisor prior to 2/28/1992**
- **Individuals meeting the qualifications of a general supervisor for high complexity testing may assess the competency of high complexity testing personnel, if this duty is delegated, in writing, by the section director.**



Technical Consultant Qualifications

GEN.53625

This requirement applies to laboratories performing moderate complexity testing, but not high complexity testing.

- **Must possess: Bachelor's degree in a chemical, physical, biological or clinical laboratory science or medical technology with at least 2 years of experience in nonwaived testing.**
- **Individuals meeting the qualifications of a technical consultant may assess the competency of personnel performing moderate complexity testing.**



Performance Assessment of Supervisors/Consultants

GEN.55525

The performance of section directors/technical supervisors, general supervisors, and technical consultants is assessed and satisfactory.

Must assess —

- Responsibilities as defined by the individual's job description must be assessed
- Duties and responsibilities delegated by the laboratory director in writing must be assessed
- Competency assessment for non-waived patient testing performed by these individuals, using all six applicable elements of competency



Supervisory Performance Assessment

Supervisory Performance Assessment Form

Name **John Doe**

Job Title **Technical Supervisor**

Responsibility Assessed	Assessment Method	Satisfactory		Date
Procedure Review	RR	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	7/30/14
Control Review	RR	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	7/31/14
Maintenance Log Review	RR	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	7/31/14
Temperature Log Review	RR	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	8/4/14
QM Indicator Review	RR	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	8/6/14
Competency Assessments	RR, DO	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	8/10/14
		Yes <input type="checkbox"/>	No <input type="checkbox"/>	
		Yes <input type="checkbox"/>	No <input type="checkbox"/>	

If any of the responsibilities are assessed as unsatisfactory please document corrective action:

Unsatisfactory Responsibility **Competency Assessments – Technical Supervisor** was not completing them in a timely manner and all six elements were not being assessed.

Corrective Action **I will review the assessments on a monthly basis to ensure they are being completed and all six elements are being assessed. I assessed three staff member's competencies with the technical supervisor to ensure he knows how to assess them properly. Documentation is attached.**



Three resources to help you simplify performing inspections:

**Need help assembling
your team?**

**Call an Inspection
Assignment
Specialist**



**Little time to sort out
travel plans?**

Call the CAP Travel Desk



Need help with inspector training?

**Access Fast Focus on Compliance,
mini-training vignettes on new
compliance topics; search
“Inspector Training”
on cap.org**



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