
	Pathology Dept. Personnel File Requirements	Document Control Number:	N/A
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		Revised Date:	
CLIA Laboratory Medical Director Signature: 		Contact:	Laboratory Compliance, QA, and Safety
Name and Title: Dr. Gregory Pomper, MD		Date Approved:	1/21/19

1) General Policy Statement:

It is the policy of Wake Forest Baptist Medical Center (WFBMC) Department of Pathology, to ensure all required documentation is present in employee files as a measure of quality assurance.

New hires must be able to produce a copy of the following documents to the hiring manager on or before their first day of work:

- An academic diploma, transcript or primary source verification (PSV) report confirming their education credentials
- If appropriate for the job description for which they were hired, a current copy of Board Certification
- If educated outside of the U.S., Foreign Equivalency documents translating the degree(s) obtained.

Without these documents, the employee will not be able to begin their assigned duties in the laboratory.

This requirement is mandated by various governing and accrediting bodies affiliated with the medical center. (Clinical Laboratory Improvement Amendments/Centers for Medicare/Medicaid Services, the College of American Pathology and The Joint Commission.)

a) **Scope:** All members of management of the Pathology Department are required to adhere to the requirements of this policy.

b) Responsible Department/Party/Parties:

- i. Policy Owner: Laboratory Compliance, Quality Assurance (QA), Safety
- ii. Procedure: Pathology Department Lab CLIA Director Business Director, Associate Directors, Section Medical Directors, Section Managers/Assistant Managers are required to adhere to the requirements of this policy.
- iii. Supervision: The Pathology Administration, Laboratory Compliance and the CLIA Laboratory Director, shall ensure compliance with the requirements outlined in this document.
- iv. Implementation: Each applicable Associate Director, Section Medical Director and/or Section Manager/Assistant Manager is responsible for ensuring compliance with processes stated in this document.

2) Policy:

NOTE: Personnel records are retained and readily available for all testing personnel, supervisory personnel, and other laboratory personnel, including all of the following information, as applicable:

REQUIREMENTS:

For Non-waived Testing and Supervisory Personnel:

1. Copy of academic diploma, transcript, or primary source verification (PSV) report confirming credentials. (Foreign Equivalency documentation if necessary)
2. Summary of training and experience
3. Certification or Board of Registry documentation
4. Description of current duties and responsibilities as specified by the laboratory director
5. Procedures the individual is authorized to perform,
6. Whether supervision is required for specimen processing, test performance or result reporting, c) Whether supervisory or section director review is required to report patient test results
7. Records of continuing education
8. Records of radiation exposure where applicable (such as with in vivo radiation testing), but not required for low exposure levels such as certain in-vitro testing
9. Work-related incident and/or accident records
10. Dates of employment
11. Record of color discrimination testing OR functional assessment, if indicated
12. Delegation of Responsibility forms and Competency Assessment if the individual holds a CLIA defined role other than Testing Personnel.

EXPLANATION & EXAMPLES OF ACCEPTABLE EVIDENCE:

NOTE: All testing personnel must have proof they meet the following requirements.

High Complexity Testing

1. Personnel performing high complexity testing must have a minimum of one of the following:
 - A. Bachelor's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; **or**
 - B. Associate degree in a laboratory science (chemical or biological science) or medical laboratory technology from an accredited institution, or equivalent laboratory training and experience meeting the requirements defined in the CLIA regulations. **Or:**
 - C. Meet other provisions defined for personnel performing high complexity testing on or before April 24, 1995 (refer to the CLIA regulations for more details)

*Grossing of specimens is considered High Complexity Testing. Testing staff must meet the qualifications of High Complexity Testing in order to perform this task.

Moderate Complexity Testing

1. Personnel performing moderate complexity testing, including non-laboratory personnel must have proof of a minimum of one of the following:
 - A. Associate degree in a chemical, physical, or biological science or medical laboratory technology from an accredited institution; **or**
 - B. High school graduate or equivalent and have successfully completed an official military medical laboratory procedures course and have held the military enlisted occupational specialty of Medical Laboratory Specialist; **or**

C. High school diploma or equivalent and have a record of training defined in the CLIA regulation 42CFR493.1423 (see NOTE 4)

3) Review/Revision/Implementation:

- a) Review Cycle: Each 2 years
- b) Office of Record: Laboratory Compliance, QA, Safety

4) Related Policies:

Documentation of Foreign Equivalency for Lab Testing Personnel

5) References: CAP Standards GEN.54400, GEN.55400, GEN.54750

6) Attachments: None

7) Review and Revision Dates:

Review Date	Revision Date	Signature