
	Department of Pathology Commitment to Quality Policy Statement and Quality Management Plan	Dept.:	Pathology
		Effective Date:	1/4/2019
		Revised Date:	4/9/2019
		Contact:	Lab Compliance, QA, Safety
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Signature: 			

1) **General Policy Statement:** The Department of Pathology of Wake Forest Baptist Health is committed to continual improvement of processes and services to achieve the highest level of quality and compliance through the minimum foundations of Clinical Laboratory Improvement Amendments (CLIA), The College of American Pathology (CAP), The Joint Commission (TJC) and Good Laboratory Practice (GLP).

a. **Responsible Department/Party/Parties:**

- i. Procedure owner: Department of Pathology
- ii. Procedure: Clinical and Anatomic sections of the Department of Pathology, Laboratory Compliance and Quality
- iii. Supervision: CLIA Laboratory Director, Laboratory Compliance, Section Medical Directors, Sections Managers/Assistant Manager
- iv. Implementation: CLIA Laboratory Director, Laboratory Compliance, Section Medical Directors, Sections Managers/Assistant Manager

2) **Definitions:** None

3) **Procedure:**

It is therefore our policy to:

- Consistently provide quality testing services supported by proper collection, transport and handling of specimens in such a way as to ensure the correct performance of laboratory tests.
- Consistently provide quality testing services supported by control data and documented laboratory testing procedures that conform to regulatory requirements
- Provide timely reporting of laboratory tests to our customers, partners, and regulatory authorities

- Provide high quality practice standards to ensure patient safety to reduce medical errors within laboratory medicine.
- Provide proper procurement and maintenance of facilities, equipment and other resources as needed for high quality practice standards, employee safety and regulatory requirements.
- Maintain a CLIA Certificate of Accreditation through successful biannual surveys conducted by survey representatives having been granted deemed authority by the Centers for Medicare and Medicaid Services (CMS).
- Maintain successful participation in proficiency testing programs approved by CLIA/Centers for Medicaid and Medicare Services (CMS) for tests that are considered regulated analytes and providing alternative means of proficiency verification for all other moderate or high complexity tests performed.
- Ensure that all personnel are qualified and competent for the tests that they perform and that all personnel familiarize themselves with quality system documentation in order to implement the policies and procedures in their work, professionally and effectively perform testing services to produce accurate and precise results.
- Ensure that our professional staff are qualified and competent by participation in required annual OPPE and/or FPPE as necessary.
- Encourage active participation of all employees in quality planning and continual improvement efforts such as LEAN.
- Show commitment to the assessment of user satisfaction, in addition to internal audit and external quality assessment in order to produce continual quality improvement.

4) Our QA Program will be implemented as indicated:

- 1. Organization** -The medical and administrative directors of the laboratory organize the laboratory into functional sections. Each functional area (or Section) of the laboratory is headed by a Manager (and/or Assistant Manager) and a Section Medical Director. All Section Managers report up to an Associate Lab Director who is headed by one Administrative Director for the Department of Pathology. The Section Medical Directors are headed by joint oversight between the Department Chair and the CLIA Laboratory Director for regulatory purposes. The CLIA

Laboratory Director assumes complete responsibility for all lab Sections within the Department of Pathology from a CLIA and CAP perspective. The outline of the organizational structure is represented by the Organizational Chart which is located in its own section of the Quality and Compliance procedure manual.

2. Personnel Resources

- a. **New Employee Orientation** - Employee orientation consists of a 1 day Hospital orientation and a Department Specific / Section Specific orientation once the employee reports to the lab area. Newly hired staff must attend the 1 day hospital orientation before starting work within the laboratory section.
- b. **New Employee Training** - Employee training is section specific. Each section maintains a training checklist(s) for the job tasks the employee will be trained to perform. The completed training checklists are signed by the employee, trainer, and section manager and/or Section Medical Director. This checklist becomes part of the employee's Department personnel file. Training within the individual sections may take on various models, such as:
 - The preceptor training model, or
 - Employee rotations through assigned benches/instruments and is
 - Training is performed by a specifically assigned technologist.

Employee training is typically completed within 3-6 months after hiring.

- c. **Competency Training and Education** –
Competency Assessment - 6 Month and Annual competency assessments are required for each new hire during the first year of employment. Assessments are based on the CLIA and CAP mandated 6 points of competency for each non-waived job task performed by the employee. Documentation of the competency assessments occur on section specific forms and are signed by the employee, trainer, and section manager and/or Section Medical Director. The competency forms become part of the employee's personnel file within the department.

In addition, the laboratory provides for competency training with regard to age-specific competency, as appropriate, and laboratory safety.

Education – The department provides multiple avenues for staff education (lectures, Grand Rounds, journal article, teleconferences, etc.) Each staff member is responsible for keeping track of their own continuing education efforts and ensuring that documentation is provided to their section manager. Documentation of continuing education becomes part of the employee's personnel file within the department.