Wake Forest Baptist Medical Center	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
Name & Title: Greg Pomper, MD, CLIA Lab Director		Date:	4/10/19
Signature: GP			

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 recourses 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.

3. **Equipment** -The laboratory has policies, processes and procedures for the selection, acquisition, installation, validation, periodic maintenance and quality assessment of equipment critical to the provision of services in the Department. Each piece of equipment is uniquely identified by Clinical Engineering before it is put in to use; calibration, maintenance, and monitoring conform to specified manufacturer requirements and/or CLIA or CAP standards. In addition, the laboratory maintains a process to investigate and follow up equipment malfunctions, failures, or adverse events with Clinical Engineering and Risk Management as appropriate. Prior to disposal or release to surplus inventory, equipment that may have been in contact with chemical, biohazardous or radioactive substances is decontaminated and decommissioned.

4. **Supplier and Customer Issues -** The laboratory administration and technical staff are responsible for supporting laboratory operations with an uninterrupted flow of material and services. The objective of the laboratory is to acquire materials of the right quality, the right quantity, the right time, from the right supplier and at the right price. The laboratory administration and staff work closely with our Purchasing department to ensure these objectives are met.

5. **Process Control**
    a. **Referral Laboratories** -The laboratory CLIA Director, the department Chair and other members of lab administration work in consultation with WFBH Medical Center and client clinicians (as appropriate) to select referral laboratories based on, but not limited to, quality, methodology, and accreditation status (a high complexity CLIA license is mandatory, CAP accreditation desirable). The Laboratory CLIA Director monitors the quality of test results by annually reviewing a sampling of test result (reports) as they are received in the laboratory. Reference laboratories are also reviewed and approved by the medical staff. A complaint by a physician concerning a test sent to a referral laboratory is referred to the Laboratory CLIA Director and an investigation is initiated with the referral laboratory.
    b. **Quality Control (QC)** - QC is the analysis of materials of known composition or reactivity in conjunction with patient sample testing to verify the performance of a test. QC materials are designed to mimic patient samples and should detect problems in instrument, reagent, software, or analyst performance. QC is predominantly a measure of precision (reproducibility) and confirms that a test system has maintained proper calibration.

For some analytes, the control material is a manufactured, purchased control product supplied in either a lyophilized or liquid form; the concentration has been both gravimetrically and analytically determined prior to distribution of the product. These materials must be evaluated in-house to determine the laboratory mean, standard deviation, and coefficient of variation before placing into service. This data is collected while running in parallel with the control product currently in use. There are some analytes that are not available in commercial preparations; hence they are prepared in the laboratory to create an appropriate control for the assay method performed. These materials must be evaluated in the same fashion as commercial products prior to placing in service.

The management of quality control occurs on a real-time basis and as a continuous tool in evaluating the reliability of test data. Technologists, supervisors, managers, and laboratory directors all contribute to this review process on a daily, weekly, and monthly basis.

The frequency of control analysis, and the preparation, reconstitution, storage conditions, and stability of specimens and reagents are described in individual procedures for each type of test. The tolerance limits for controls are established by individual sections. Values which fall outside these ranges must be evaluated according to the internal control rules used in individual sections. Violation of the QC rules results in review by the supervisor and/or director and may result in rejection of the analytical run. The run must be inspected to determine the cause for error. After resolving the problem that caused the QC exception, the entire run may need to be repeated, along with QC evaluation. Quality control records are maintained for a minimum period of 2 years (5 years for Transfusion Medicine).

c. **Proficiency Testing (PT) -** Proficiency testing is defined as periodic testing of samples whose composition or reactivity is unknown to the laboratory. PT samples are usually provided by an external agency that "knows" what an analytic result is expected to be or establishes the "correct" answer based on aggregate results from large numbers of laboratories participating in the survey.

In the clinical laboratory, each section (as appropriate) is enrolled in a CMS-approved proficiency testing program for all tests for which CAP or other CMS approved proficiency testing is available. Results are evaluated by the survey provider against peer group responses. Internally, results are reviewed by the section manager/assistant manager and the laboratory

medical director. Outliers are investigated, corrective action is taken, and a report is made to the Lab Compliance and Quality section via the CAPA process. PT performance is also documented monthly by each section as part of their Quality Indicator reports.

Survey samples are to be integrated within the routine laboratory workload, and the samples analyzed by personnel who routinely test patient samples, using the same methods. The educational purpose and documentation of proficiency is best served by a rotation that allows all technologists to be involved in the proficiency testing program. Replicate analysis of survey samples is acceptable only if patient specimens are routinely analyzed in the same manner.

In accordance with CMS regulations, laboratories are forbidden to "engage in any inter-laboratory communications pertaining to the results of proficiency test samples" or to "send PT samples or portions of samples to another laboratory for analysis."

For analytes where graded proficiency testing is not available, performance must be checked at least semiannually using an alternate performance assessment system. These procedures include participation in ungraded proficiency survey programs, split sample analysis with reference or other laboratories, split samples with an established in-house method, certified materials, regional pools, clinical validation by chart review, or other suitable documented means. It is the responsibility of the laboratory section director to define such procedures, as applicable, in accordance with good clinical and scientific laboratory practice.

If laboratory testing of a PT challenge does not produce acceptable results, the cause of the error must be investigated and corrected. There are several types of errors: methodological (the source is within the analytic system); technical (the source is attributable to performance within the laboratory); clerical (errors made in completing the forms returned to the surveyors for processing, such as transcription errors); survey (errors attributed to the survey materials or to the directions accompanying the survey material, such as matrix effects, unstable survey samples, a validated deviation from the consensus, or survey samples that did not arrive on time); or unexplained. An error should be designated as unexplained only after a full investigation has been completed, eliminating every other possibility of error.

Unacceptable performance of PT challenges are required to have a CAPA form completed.

6. **Documents Control -**Each section manager and medical director is responsible for ensuring that policies and procedures for the section are current, that appropriate revisions occur annually or more often, as needed, and that all lab staff are kept abreast of procedural changes through a method change notification or staff procedure sign off. New method procedures require CLIA Lab Director and Section Medical Director (or designee) signature prior to implementation. Procedures must be retained for a minimum of 3 years after discontinuation (10 years for Transfusion Medicine). WFBH utilizes the Title 21 Software package for document management, review, and retention.

7. **QA Monitoring -** Each laboratory section has identified indicators to monitor quality of operations. Indicators may be pre-analytic, analytic, or post-analytic. When appropriate, trends are evaluated over time to evaluate deviation from baseline. Regular reports are made during monthly quality assurance departmental meetings regarding performance and improvement opportunities. Refer to the Department of Pathology Combined QA/QI policy for a list of quality metrics as defined by each section.

8. **Occurrence Management -**The laboratory is actively involved in capturing and analyzing information from nonconforming events to identify systematic laboratory problems, both internally and externally. We refer to this process as the Department CAPA (Corrective Action/Performance Action) Process. The following methods are used to detect errors:

    - Random Review Error detected within laboratory section by predetermined internal review processes and established perimeters.

    - Laboratory Detection Error detected by means other than a random review (internal).

    - External Detection Error reported by a physician, nurse, or other customers/individuals outside the laboratory (Event Reporting System).

    Each laboratory section is responsible for capturing/developing a system for detecting errors using the above methods. A summary of laboratory occurrences (including trends) is reviewed at the Laboratory Compliance and Quality section on

a monthly basis and reported through the monthly Department of Pathology QA/QI meetings.

9. **Assessments/Inspections** -The laboratory participates in the College of American Pathologists (CAP) Laboratory Accreditation Program. The accreditation process from CAP includes an unannounced inspection by a team of professionals from a peer organization every two years. During the two year cycle, the CLIA Lab Director is responsible for assembling a team to provide inspection services for another laboratory similar in size and complexity to WFBH. The Laboratory Compliance and Quality Officer, in conjunction with the CLIA Lab Director, are responsible for all inspection submissions and oversees compliance with the certification requirements.

   During the off year of the CAP inspection cycle, the laboratory participates in a required Self- Inspection process. During the self-assessment, members of the Resident Team, the Laboratory Compliance and Quality Staff and other lab team members from affiliate laboratories within the WFBH system are asked to participate and serve as inspectors for the self-inspection. All deficiencies and/or recommendations noted during the self-assessment are reviewed and corrected in the same manner as an official CAP inspection.

   Sections of the laboratory undergo additional external inspections as listed below:

   Transfusion Medicine

   - Food and Drug Administration, unannounced, variable
   - AABB, unannounced, every two years
   - FACT, every three years

   Immunogenetics

   - American Society for Histocompatibility and Immunogenetics, unannounced

   The Medical Center

   - Our Medical Center is accredited by the Joint Commission (TJC). TJC accepts the CAP accreditation for the laboratory-specific portion of the standards. The laboratory supports WFB Health System's efforts to comply with TJC hospital accreditation standards.
   - Point of Care testing performed at the Medical Center by non-laboratory staff is subject to the Hospital TJC Accreditation process under the Waived Testing standards.

10. **Process Improvement** -The quality program of the Department currently includes a number of performance improvement initiatives for important laboratory services. The laboratory utilizes the LEAN process to approach and address improvement initiatives. Each laboratory section is responsible to select their own PI initiatives to improve performance. LEAN projects and processes are led by the section managers with oversight provided by Lab Compliance and Quality, the Manager of Safety, the CLIA Lab Director and Lab Administration. Regular section updates are provided monthly as part of the QA/QI Department meetings.

11. **Facility and Safety** -The laboratory has implemented appropriate processes to minimize and respond to environmentally related risks to the health and safety of employees, residents, volunteers, patients, and visitors. A Department safety committee meets 4 times a year in order to:
    - Keep all sections of the laboratory current with safety related information;
    - Ensure safety related tasks are occurring on schedule;
    - Review revised safety regulations, policies, and training materials;
    - Conduct safety related performance improvement initiatives;
    - Address safety concerns;
    - Clarify safety policies;
    - Evaluate incident and accident reports for the Department;
    - Review and evaluate the effectiveness of the laboratory's Chemical Hygiene Plan; and
    - Make recommendations to the Laboratory Executive Committee and the CLIA laboratory director related to safety policies.

    The Department strives to proactively address patient safety concerns. Awareness of TJC patient safety goals are evaluated and included in the safety practices where applicable.

12. **Information Management** -The Department has policies and procedures for data access security and transfer integrity. Access to the laboratory information system, Beaker/EPIC, is limited to authorized users by various security measures which include, but are not limited to:
    - Job responsibility based security profiles/user groups
    - User profiles
    - Operator codes
    - User identification codes
    - Passwords

The Information Technology Department along with the CLIA Laboratory Director, the Data Security Officer and/or Systems Manager must approve authorization of users. The system has security standards designed to restrict unauthorized direct or remote data access and the ability to identify individuals responsible for inappropriate access. All computer network connectivity is maintained in a secure environment following both the Medical Centers policies with the use of:

- Anti-virus protection
- Anti-spyware protection
- Operating system critical patch updates.

System vital checks are verified quarterly and/or following any scheduled or unscheduled computer downtime as a method to verify:

- Integrity of stored data
- Access criteria remains intact
- Security continues to function as required

A risk assessment and validation of the computer system is performed as required by regulatory agencies for all changes or upgrades. Each department is responsible for the development, training and practice of computer downtime procedures. The laboratory complies with all HIPAA regulations related to the privacy and confidentiality of patient information. The laboratory defaults to the IT Department, Data Security Office and Privacy Security Officer to periodically monitor compliance with HIPAA, Privacy and Patient Confidentiality procedures.

13. **Quality Oversight** -The Department of Pathology and Laboratory Medicine's quality management plan is overseen by the Laboratory Compliance and Quality Officer, the CLIA Laboratory Director and Laboratory Administration. QA/QI meetings are scheduled to occur on a monthly basis to include all sections of the Department of Pathology. Each laboratory section is represented by a laboratory manager/assistant manager and/or director or their designee. Minutes are recorded, electronically transmitted, and reviewed; the approved copies are retained in a Shared Access Lab file on the network. The CLIA Laboratory Director is responsible for reviewing in a timely manner the monthly QA/QI data submitted by each section.

    Once the meeting minutes are reviewed and approved by the CLIA Lab Director, the minutes are forwarded to the Medical Center's Quality and Process Improvement Team to be included in their higher level, Quality Improvement/Process Improvement (QAPI) report to Medical Center Leadership.

14. **Quality Planning** -The objectives, organization, comprehensiveness, and effectiveness of the laboratory quality management program are evaluated at least annually, and the program revised as necessary. This evaluation is performed jointly by the Laboratory Compliance Officer, the CLIA Laboratory Director, Section Medical Directors, Section Managers or other individuals who have appropriate delegation. The evaluation is shared with other members of the Lab Administrative team/Lab Executive Committee. Focus will be placed on areas of technological change and organizational change, as well as recurring problems.

5) **Review/Revision/Implementation:**
   a. Review Cycle: 2 years
   b. Office of Record: Department of Pathology

6) **Related Policies:** N/A

7) **References, National Professional Organizations, etc.:**

- CAP Standard GEN.20325
- Application of a Quality Management System Model for Laboratory Services; Approved Guideline—Third Edition. GP26-A3 NCCLS, 2004.
- A Quality Management System Model for Healthcare; Approved Guideline—Second Edition. HS1-A2 NCCLS, 2004.
- Quality Manual Preparation Workbook for Blood Banking, 2nd Ed. Lucia M. Berte 2005. AABB.
- Code of Federal Regulations, Title 49, Part 493
- Quality Management In Clinical Laboratories, CAP, 2005
- Laboratory Accreditation Manual, most current copy, College of American Pathologists, 325 Waukegan Road, Northfield, IL, 60093.
- The Key to Quality-Fundamentals for Implementing a Quality Management System in the Clinical Laboratory, CLSI, 940 West Valley Road, Suite 1400, Wayne Pennsylvania, 19087, 2006.
- Standards for Blood Banks and Transfusion Services, most current edition, AABB, Bethesda, Maryland. S

8) **Attachments:** N/A

9) **Revision Dates:**

Review Date	Revision Date	Signature
	4/9/2019 – Revisions include the entire new section of #4. The new section	MH

	includes specific details explaining the essential elements of our Quality Management Plan and our implementation strategy for each of these elements.	