| Wake Forest Baptist Medical Center | Quality Assurance Policy for Anatomic and Clinical Lab Reports | Dept: | Pathology |
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| | | Effective Date: | July 2007 |
| | | Revised Date: | Feb 18, 2019 |
| | | Contact: | Lab Compliance, QA, Safety |
| Name & Title: CLIA Laboratory Director | | Date: | 3/12/19 |
| Signature: | | | |

1) **General Policy Statement:** To define the procedure for compliance with CAP and CLIA requirements regarding the quality of laboratory reports.

   a. **Purpose:** The work product of the lab is a timely, accurate, readable report. These three elements of all WFBH clinical and anatomic lab reports (paper and electronic) will be reviewed and approved by the CLIA Laboratory Director (or designee who meets CAP qualifications for Laboratory Director – typically Section Medical Directors) at least every two years in accordance with CAP Standards GEN.41067 and GEN.48500.

   b. **Responsible Department/Scope:**
      i. Procedure owner/Implementer: Department of Pathology
      ii. Procedure prepared by: Laboratory Compliance, QA and Safety
      iii. Supervision: Department of Pathology CLIA Lab Director, WFBH Beaker Team, Section Medical Directors, Section Managers/Assistant Managers, Laboratory Compliance/QA
      iv. Implementation: Department of Pathology CLIA Lab Director, WFBH Beaker Team, Section Medical Directors, Section Managers/Assistant Managers, Laboratory Compliance/QA

2) **Definitions:**

For the purposes of this policy, the following terms and definitions apply:

- **WFBMC:** Wake Forest Baptist Medical Center and all affiliated organizations including Wake Forest University Health Sciences (WFUHS), North Carolina Baptist Hospital, all on-site subsidiaries as well as those off-site governed by WFBMC policies and procedures.
- **Policy:** As defined in the Policy on Creating and Amending Policy, a statement of principle that is developed for the purpose of guiding decisions and activities related to governance, administration, or management or care, treatment, services, or other activities or WFBMC.

3) **Policy Guidelines:**

General Requirements:

The department of Pathology will coordinate compliance with this regulatory requirement, which covers all test reports (paper or electronic) generated within clinical and anatomic pathology as well as those that are provided through the laboratory by interfaced reference laboratories.

1) Monitoring:
    a. Review of lab reports in Beaker, Wake One, SCC, CoPath, and Wake Patient Portal will be performed at the following intervals:
        - Biannually (at a minimum)
        - Following all major upgrades in Beaker, Wake One, SCC, CoPath and interfaces affecting laboratory results.
        - Following any notification from a reference lab indicating a change in report format
        - Review when complaints and requests are received from users (MD, RN, PA, etc.)
        - Review when problems are identified by the laboratory personnel and/or informatics staff.
        - Prior to implementation/go-live of any new laboratory or Point of Care tests
        - Prior to implementation/go-live of any new LIS or interface (including Point of Care)

    b. Members of the Beaker/LIS Informatics Team will assist the laboratory with requested report audits as deemed necessary.

    c. Paper and electronic versions of laboratory reports must meet CLIA and CAP standards and must contain the following elements:
        (1) Results reported from calculated data.
        (2) Results and patient-specific data electronically reported to network or interfaced systems.
        (3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.
        (4) Test report information maintained as part of the patient's chart or medical record must be readily available to the laboratory and to CMS or a CMS agent upon request.
        (5) The test report must indicate the following:
            - For positive patient identification, either the patient's name or identification number, or a unique patient identifier and identification number.
            - The name and address of the laboratory location where the test was performed.
            - The test report date.
            - The test performed.
            - Specimen source, when appropriate.

- The test result and, if applicable, the units of measurement or interpretation, or both.
- Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

2) **Review**

a. The CLIA Lab Director of the laboratory must review and approve reports prior to release in the following situations:
   - Implementation/go-live of a new test
   - Prior to implementation/go-live of a new LIS
   - Prior to implementation /go-live of a new EMR
   - Prior to implementation/go-live of any interface that will be utilized for laboratory tests (including Point of Care)
   - Following in major upgrades to any LIS, EMR or interface involving laboratory test results
   - Following notification of a reference lab report format notification change.
   - Bi-annual required review.

b. Individuals within the sections who meet the qualifications for laboratory director (typically Section Medical Directors) may review and approve report formats in the following situations:
   - Review when complaints and requests are received from users (MD, RN, PA, etc.)
   - Review when problems are identified by the laboratory personnel and/or informatics staff.
   - Prior to implementation/go-live of any new laboratory or Point of Care tests, before the CLIA Lab Director approves
   - Prior to implementation/go-live of any new LIS or interface (including Point of Care), before the CLIA Lab Director approves
   - Following change requests to ranges, units of measure, etc.
   - Following routine report review audits.

c. Schedule:
   Reports must be reviewed at a minimum of every 2 years regardless of changes, complaints or system upgrades. The CLIA Laboratory Director must review and approve reports at least every 2 years.

   For changes or situations as defined in 1(e) above, a designee who meets laboratory director qualifications may review and approve reports.

d. Corrective Action/Follow-up:
   Any deviations from regulatory required formatting noted will be documented using the laboratory CAPA process. As part of that process immediate steps will be taken to proceed with corrective actions through initiation of Help Desk tickets to bring in the support of IT counterparts.

e. Follow-up:
Resolution of problems will be reported to and verified through the CAPA process. The Laboratory QA department will monitor and track the problems and report as appropriate through the Department of Pathology Quality Assurance Monthly reports.

f. This process involves only reports for individual patient test results. Institutional quality measures, benchmarking, and other aggregate data reports will be handled according to the needs of the requesting department or individual.

**3) Revision/Implementation:**

All procedures must be reviewed at least every 2 years.
House of Record: Department of Pathology- Laboratory Compliance/QA Section

**4) Related Procedures:**

*CAPA Procedure*
*Beaker/IT procedure*

**5) References:**

CAP Standards: GEN.41067 and GEN.48500
CLIA Standard 493.1291

**6) Attachments:** None

**7) Revised/Reviewed Dates and Signatures:**

| Review Date | Revision Date | Signature |
|---|---|---|
| | 2/18/2019- MH revised to include references to CAP standards and formatting changes | |
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