Washington State Office of Laboratory Quality Assurance

DEVELOPING A QUALITY ASSURANCE PLAN

July 2007

OVERVIEW

Each medical test site must establish and follow written policies and procedures for a comprehensive quality assurance (QA) program. The QA program must be designed to monitor and evaluate the ongoing and overall quality of the total testing process (preanalytic, analytic, postanalytic). The medical test site's QA program must evaluate the effectiveness of its policies and procedures; identify and correct problems; assure the accurate, reliable, and prompt reporting of testing results; and assure the adequacy and competency of the staff. As necessary, the medical test site must revise policies and procedures, based on the results of those evaluations. The medical test site must meet the standards as they apply to the services offered, complexity of testing performed and test results reported, and the unique practices of each testing entity. All quality assurance activities must be documented.

For each of the following items, describe what you actually do - keep it simple and meaningful for your lab. You can have one plan or many individual policies, depending on what works for you.

1. ESTABLISH & IMPLEMENT A WRITTEN QA PLAN, INCLUDING POLICIES & PROCEDURES TO:

a. Monitor, evaluate, review:

Quality control results

- What kinds of controls are used?
- How are control ranges established?
- What criteria are used to decide if test run is acceptable?
- What is to be done when controls are outside limits?
- What systems are used to evaluate shifts and trends?
- Who reviews QC data, how often, what's done when problems are noted?

Proficiency testing results

- Performed by all staff?
- Handled like patient samples?
- How are failures investigated, documented?
- How do you evaluate your performance when your results are ungraded?
- Who reviews PT results?
- Are PT samples used to assess personnel competency?

Patient test results

- Describe your reporting system
- How are patient results reviewed for accuracy, clarity, transcription errors, improbable values?
- Are results correlated with other findings?
- Do you have a system for reporting critical values, corrected reports?

Biannual verification of accuracy

- What tests are not covered by PT (non-regulated analytes)?
- Define frequency - minimum 2 samples twice per year
- How is biannual verification done?
- Set criteria for acceptable agreement between split samples

Biannual evaluation of relationship of test results between methods

Describe instruments or methods
Describe how often - minimum 2 samples twice per year
How is biannual evaluation done?
Set criteria for acceptable agreement between instruments or method

b. Identify and correct problems

Define systems available, who reviews, how often
- QC results
- PT results
- Patient results
- Troubleshooting, problem logs
- Incident reports
- Corrected reports
- Complaints
- Patient redraws

c. Establish, maintain accurate, reliable, prompt reporting of test results

Who reviews reports for accuracy, clarity?
Do all results have units of measurement, normal ranges?
How are phoned reports handled, documented?
How are corrected reports handled, documented?
Are critical limits defined? How are they handled, documented?
What are your expected turnaround times - STATs, routines?
What is your system to track and report send-out test results?

d. Verify all tests conform to specified performance criteria in quality control

Procedures are available, are correct and staff adhere to them
Performance criteria (for QC, calibration, linear limits, etc) are written and available to staff
QC, calibrations, linear limits, instrument performance checks are performed on schedule, are acceptable or patient results are not reported
Trends are noted and corrected

e. Establish, maintain adequacy, competency of technical personnel

Write job descriptions, define duties and responsibilities
Develop orientation and training checklists
How is ongoing competency assessed?
(Direct observations, review of QC, PT, problems, reports, evaluations)
How is competency documented? (Semiannually for new employees, annually thereafter)
Continuing education documentation

2. THE QA PLAN INCLUDES MECHANISMS OR SYSTEMS TO:

a. Establish & apply criteria for specimen acceptance & rejection

How are samples labeled?
What do you do if specimens are collected in incorrect containers?
What do you do if there are there are time delays in delivery of specimens to lab?
How do staff know what's acceptable, unacceptable for each test performed?

b. Notify individuals as soon as possible of life-threatening results

Write a critical limits (panic values) policy
Define limits with your Director and medical staff
What's done (repeat, confirm value)?
Who's called, how do you document?

c. Assess problems identified during QA review & discuss with staff

What QA reviews are done?
Incident reports, complaints, corrected reports, problem logs, PT performance, personnel issues
Problems with specimen submission, clarity of orders, turnaround times
How are reviews shared with staff?

d. Evaluate reporting systems-Accurate, reliable reporting, transmittal, storage, retrieval of data

How are results reported, charted in your setting?
Describe computer reporting systems
Describe transmittal of results from other labs - onsite printers, faxed results, phoned results
Describe archiving of results
Define record retention - Where, how long?

e. Document all actions taken to identify and correct problems and that they are effective in correcting the problem

f. Issue corrected reports

Write a corrected report policy describing how this is done in your system

g. Provide instructions for specimen collection, handling, preservation, transportation

These should be available to nurses, doctors, clients
Where are these for each test?
How are these updated when tests or methods change?

h. Provide clients updates of testing changes affecting test results or interpretation

For changes in methods, normal ranges, detection limits, interpretation of results, specimen requirements
Describe how Director is made aware of changes
Describe how Director shares this with other medical staff or clients