

# ELABORATIONS

News and Issues for Washington's Clinical Laboratories

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## Testing Personnel Competency Assessment

by Linda Parisi, DOH/LQA

The laboratory director is ultimately responsible to ensure that laboratory staff have the proper education, experience, and training as well as to establish an ongoing competency assessment program.

Competency assessment does not have to consume a large amount of time, effort, or money. An overall laboratory policy should be in place that defines the components that will be used to assess the ongoing competency of the testing personnel in the facility. The main goal of an ongoing competency assessment program is to document the competency of the testing personnel to insure quality patient laboratory test results.

The Medical Test Site (MTS) licensing program and the Clinical Laboratory Improvement Amendments of 1988 (CLIA) rules require the director to document competency of laboratory staff at least annually. New employees must have initial training documented on a checklist and competency assessment semi-annually the first year, and annually thereafter. Competency assessment can provide a means to assure management and the public that the testing personnel are truly competent. Competency assessment can provide continuing education, be part of a performance evaluation, and assist with the introduction of new or revised policies and procedures.

A process to assess an employee's competency can include, but is not limited to, the following components:

1. Direct observation of routine patient test performance, including patient preparation, specimen collection, handling, and processing;

2. Monitoring the recording and reporting of test results (may include an audit of patient charts for accuracy);
3. Review of preliminary test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records;
4. Direct observation of performance of instrument maintenance and function checks (compared with instructions provided by the manufacturer);
5. Assessment of test performance through testing previously analyzed specimens (repeat testing), internal blind testing samples, or external proficiency testing samples; and
6. Assessment of problem solving skills (review of problem logs, complaints, incident reports, etc.).

Competency assessment should encompass all three phases of the testing process (pre-analytic, analytical, and post-analytic). Documentation of competency assess-

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### Practice Guidelines

The following practice guidelines have been developed by the Clinical Laboratory Advisory Council. They can be accessed at the following website:  
[www.doh.wa.gov/lqa.htm](http://www.doh.wa.gov/lqa.htm)

Anemia	Lipid Screening
ANA	PAP Smear
Bioterrorism Event Mgmt	Point-of-Care Testing
Bleeding Disorders	PSA
Chlamydia	Rash Illness
Diabetes	Red Cell Transfusion
Group A Strep Pharyngitis	Renal Disease
Group B Streptococcus	STD
Hepatitis	Thyroid
HIV	Tuberculosis
Infectious Diarrhea	Urinalysis
Intestinal Parasites	Wellness

# Minimum Method Validation Process - Moderate Complexity Testing

by Susan Walker, DOH/LQA

Validation of new instruments must be performed prior to reporting patient results. This validation must be performed at the facility where the instrument is to be used. The following is a brief summary of the validation requirements for moderate complexity testing.

## Accuracy Check

- Analyze two levels of assayed control material ten (10) times each over several days.
- All control values should fall within the expected QC range.
- Calculate the average (mean) for each level. These values should be close to the midpoint of the range.

## Precision Check

- Using a scientific calculator, calculate the standard deviation (SD) and the coefficient of variation (CV) from your accuracy check values above for each level.
- Calculate the %CV:  $\%CV = SD/average\ (mean) \times 100$ .
- Determine whether the CV meets the manufacturer's specifications for the test.

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## Website addresses:

**DOH home page:** <http://www.doh.wa.gov>  
**LQA home page:** <http://www.doh.wa.gov/lqa.htm>  
**PHL home page:**  
<http://www.doh.wa.gov/EHSPHL/PHL/default.htm>

**Correlation Study with Patient Samples:** Perform testing on at least ten (10) patient samples for your new instrument that span your reportable range (low – mid – high) and compare these values with your old/current method or with your reference laboratory. The Director must approve the agreement of the results based on the clinical expectations and method accuracy/precision claims.

## Reportable Range Check

- Check the high and low values that represent your reportable range. You may use calibrators (run as patients) or a linearity set to do this. You can also use patient specimens that have been tested by a reference method, or proficiency testing specimens for this check.
- Analyze, in duplicate, reference materials that reflect the minimum and the upper limits.
- Compare the values. The Director must approve the agreement of the results, based on clinical expectations. These must be used to set the lowest limit and upper limit for reporting patient values.

**Reference Range Check:** The manufacturers usually provide this information. The reference range should be provided with the patient test results. Have your Director review and approve the results. Assure they are appropriate for your patient population.

**Calibration:** Follow the manufacturer's instructions for the calibration of the instrument if required for your instrument.

If your instrument is to use a whole blood fingerstick specimen, please call your surveyor for additional suggestions for completing your validation.

The minimized instrument validation process information has been placed on the LQA website at the following address: <http://www.doh.wa.gov/lqa.htm>.

## Personnel Competency Assessment, cont'd from page 1

ment activities should be done every 12 months and should be available for review at the time of inspection.

The ongoing competency assessment program should have a contingency plan stating how a staff member who does not pass a competency assessment would be brought back to “competent” status. In general, if an employee fails a competency on a particular procedure, the employee should not perform that procedure until corrective action steps have been taken and is finally deemed competent to perform that procedure again.

The laboratory director is ultimately responsible for all laboratory activities including employee selection, competency assessment, test performance, quality control, quality assurance assessment, etc. Since the laboratory director and/or laboratory supervisor should be involved in the day-to-day activities in the laboratory, they should be aware of problem areas that would make good opportunities for testing personnel competency assessment.

## MTS License Renewal Activities Near Completion

Have you returned your Medical Test Site (MTS) license renewal application yet? Time is running out! MTS renewal applications were due in the LQA office by April 16. All facilities with outstanding renewal applications were notified by fax or e-mail in the middle of May.

**How will I know if my updated MTS license application has been received by LQA?** If your MTS renewal application has been received by LQA, you will have received a fee letter indicating the license fee amount due for your particular classification of license.

**I no longer need a MTS license for my facility. What should I do?** If you no longer need a MTS license for your facility, notify the LQA office at (206) 418-5600 that you no longer need a license and the reason why.

**What happens if I do not renew my MTS license?** MTS licenses will expire on June 30, 2007, unless you have already renewed your license. On July 1, 2007, the MTS license for those facilities that have not returned their MTS renewal applications will be “CLOSED” in the MTS database. The CLIA number will also be terminated in the Centers for Medicare & Medicaid Services (CMS) database.

**How will termination of my CLIA number affect my reimbursement for billing for laboratory tests performed in my facility?** The information in the CMS database is accessed by government reimbursement agencies, such as Medicare and Medicaid, who use the information to reimburse medical claims to providers. If the CLIA number is not active, the claims for laboratory testing will be denied.

**I received my fee letter for my MTS license renewal, but I have not received an updated license. What should I do?** The first thing to do is to check with your bookkeeper to see if the check for the MTS license renewal has been issued and cashed. If you have not received your updated MTS license with the expiration date listed as June 30, 2009, contact the LQA office at (206) 418-5600. If your check has been issued within the last few days, your license should be issued shortly.

**When is my MTS license renewal payment due?** Washington State requires that the renewal license fee be paid at least thirty days before the license expiration date [WAC 246-338-024(1)]. Therefore we must receive your payment by **June 1, 2007**. All facilities with outstanding fee payments were notified by fax toward the end of May.

**What happens if I do not pay my MTS license fee?** MTS licenses will expire on June 30, 2007, unless you have already renewed your license. On July 1, 2007, the MTS license for those facilities that have not returned their MTS renewal license fee will be “CLOSED” in the MTS database. The CLIA number will also be terminated in the Centers for Medicare & Medicaid Services (CMS) database.

## MTS Relicensing

**Current MTS licenses will expire on June 30, 2007**

**Your MTS license and CLIA # will automatically be terminated on July 1, 2007, if we have not received your renewal application by June 1. See the article on page 3. Contact the LQA Office at (206) 418-5600 if you have questions.**

### Calendar of Events

**PHL Training Classes:**

(<http://www.doh.wa.gov/ehsphl/phl/training/train.htm>)

**Packaging & Shipping of Infectious Substances**

June 29 Mount Vernon

**Northwest Medical Laboratory Symposium**

October 24-27 Seattle

**14th Annual Clinical Laboratory Conference**

November 12 Seattle

**2008 WSSCLS/NWSSAMT Spring Meeting**

April Everett

Contact information for the events listed above can be found on page 2. The Calendar of Events is a list of upcoming conferences, deadlines, and other dates of interest to the clinical laboratory community. If you have events that you would like to have included, please mail them to ELABORATIONS at the address on page 2. Information must be received at least one month before the scheduled event. The editor reserves the right to make final decisions on inclusion.