

# ELABORATIONS

News and Issues for Washington's Clinical Laboratories

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## 2013 Top 10 Most Frequently Cited Deficiencies

by Linda K. Parisi Department of Health/LQA

The Washington State Department of Health Laboratory Quality Assurance (LQA) team inspected 299 laboratories in 2013 under the Medical Test Site (MTS) licensing program. This article outlines the top 10 deficiencies cited during 2013. There was a three-way tie for the 10th most frequently cited deficiency so all three are listed for a total of 12 citations. The MTS Washington Administrative Code (WAC) citation appears after each item.

**No. 1. No remedial Action Taken** {WAC 246-338-080(3)}: This deficiency will result from a lack of appropriate documentation. Document all remedial action in response to failures in quality control, quality assurance, personnel, proficiency testing, and transfusion reaction investigation. This deficiency is also cited when the laboratory fails to recognize that it has a failure and/or doesn't take effective action to correct the problem.

### Compliance Tips:

- Establish an effective mechanism to recognize that problems exist and document appropriate corrective action.
- Review documentation on a regular basis and record that review.
- Document, document, and document.

**No. 2. Personal Competency Evaluation** {WAC 246-338-060(3)(b)(iv)}: The MTS director must evaluate, verify, and document the competency of technical person-

nel who perform test procedures and report test results.

### Compliance Tips:

- Have a written policy defining personnel competency testing for your facility.
- Make sure that your policy incorporates direct observation, review of records, performance of maintenance, assessment of test performance through testing previously analyzed samples, blind samples, or external proficiency testing samples, and problem-solving skills.
- Document the initial training of new testing personnel, assess competency at about six months and annually thereafter.
- Document remedial action for personnel failing the competency assessment.

continued on page 3

### Inside This Issue

- 2 Patient Access to Test Reports
- 3-5 2013 Top 10 Deficiencies, cont'd
- 6 Individual Quality Control Plans (IQCP)/Calendar of Events

## Practice Guidelines

The following practice guidelines have been developed by the Clinical Laboratory Advisory Council. They can be accessed at the [LQA website](#).

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

# Patient Access to Test Reports

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Washington has had regulations (chapter 70.02 RCW) in place since 1993 that allow patients access to their medical information including laboratory test results. It is important that laboratories have a secure and defined process to deliver patient laboratory results to providers and patients upon request.

On the federal level, the Department of Health and Human Services (HHS), the Centers for Medicare & Medicaid Services (CMS), and the Office of Civil Rights (OCR) supported patients having access to their personal health information, including access to their laboratory test reports. However, in order for this to be achieved, the Clinical Laboratory Improvement Amendments (CLIA) Program and Health Insurance Portability and Accountability Act (HIPAA) needed to be updated.

The CLIA regulations at 493.1291 have been revised to specify that upon a request by a patient (or the patient's personal representative), the laboratory may provide patients, their personal representatives, and those people

specified under 45 CFR 164.524(c)(3)(ii) as applicable, with access to the completed test reports. There is the additional requirement that the laboratory needs to have an authentication process to be able to verify the identity of the patient.

The HIPAA rule was amended at 45 CFR 164.524 to remove the exceptions that relate to CLIA and affect a person's right of access. The change to 164.524 preempts any contrary provisions of State law and aligns the changes with the Privacy Rule and CLIA regulations with the HHS goal of improving a people's access to their health information.

The federal **Final Rule** changes took effect on April 7, 2014. Laboratories must be in compliance with these requirements after October 6, 2014. Washington laboratories should already be in compliance because of the 1993 Washington law.

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**Website access:**

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## 2013 Top 10 Deficiencies, cont'd from page 1

**No. 3. Proficiency Testing to include Proficiency Testing (PT) failures** {WAC 246-338-050(1)(a)}: Participation in proficiency testing (PT) is required for all regulated analytes tested in your laboratory. The [LQA](#) website has information about PT requirements and a list of the regulated analytes under the “MTS Proficiency Testing” option on the left side of the screen. For non-regulated analytes, the laboratory can enroll in PT or use an alternative method (Biannual Verification) to comply with the regulation. PT is not required for waived tests, but is recommended as good laboratory practices.

Compliance Tips:

- Enroll in PT for all regulated analytes each year.
- Enroll in PT or develop a Biannual Verification (BV) policy for non-regulated analytes; test at least two samples per analyte twice per year.
- Check the attestation statements for signatures of the laboratory director (or designee) and the testing personnel.
- Document the review of PT or BV results and any remedial action to correct problems or failures.

**No. 4. Record Retention** {WAC 246-338-070(8)}: The MTS must retain records, slides, and tissues as described in Table 070-1, under storage conditions that ensure proper preservation.

Compliance Tips:

- Write and follow a record retention policy for your facility.
- Records must be available during onsite inspections. If some records are stored offsite, be prepared to quickly retrieve records requested by the inspector.

**No. 5. Temperature Records** {WAC 246-338-090(2)(a)}: Establish written criteria for and maintain appropriate documentation of temperature-controlled spaces and equipment. Include the monitoring of room temperature for reagents stored at room temperature or if the manufacturer specifies a specific temperature range. Temperature storage and ranges are found in the package insert and/or on the reagent box.

Compliance Tips:

- Establish acceptable temperature ranges.
- Record temperatures on each day of business, including room temperature if specified for reagents, supplies, or equipment.
- Document corrective action taken when temperatures are outside acceptable limits.
- Re-record temperatures several hours after any adjustment to the thermostat.
- Make sure that thermometers are calibrated and reading accurately.

**No. 6. Calibration/Calibration Verification** {WAC 246-338-090(7)(a)}: Calibration and calibration verification is required for moderate and high complexity testing as described in the MTS WAC Table 090-2. There are exceptions to the Calibration Verification regulation that are carefully defined under the “Supplemental Material” option on the [LQA](#) website.

Compliance Tips for Calibration:

- Perform at installation of new instruments or methods.
- Review manufacturer’s literature for required calibration frequency.
- Perform when calibration verification fails to meet acceptable limits.
- Retain pre- and post-calibration material.
- When controls are outside limits or exhibit trends or shifts.
- Perform upon return of equipment sent out for repair.
- Retain package insert from the calibration material.

Compliance Tips for Calibration Verification:

- Have a written procedure and schedule defining which methods require calibration verification.
- Perform calibration verification
  - Every six months

## 2013 Top 10 Deficiencies, cont'd from page 3

- o When there is a complete change of reagents (new lot numbers).
- o When controls are outside limits or exhibit trends or shifts.
- o When major preventive maintenance is performed or critical instrument parts are replaced.

**No. 7. Testing Site Information on Reports** {WAC 246-338-070(3)(c)(i)}: The name and address of the MTS, or when applicable, the name and address of each testing site performing each test must be on the final patient report.

Compliance Tips:

- Print and review reports for accuracy of test results and the location of test performance.
- Review reference laboratory results upon receipt for location of test performance.
- If there is electronic transmission of results from a reference laboratory, be sure to confirm that each test or group of tests is identified as to location of actual performance.
- Validate that all results have the correct location of test performance for new information or medical patient records systems.

**No. 8. Expired Reagents** {WAC 246-338-090(6)(a)}: The MTS must use materials within their documented expiration date. This deficiency will be cited when supplies or reagents are used beyond their expiration date. This may also be cited when supplies or reagents requiring a change of expiration date upon opening or removal from storage are not changed or are used beyond their “new” expiration date.

Compliance Tips:

- Ensure that staff members are aware of the regulation stating that materials must be used within their documented expiration date or new expiration date if changes upon opening or removal from storage.
- Establish a procedure to check expiration dates of supplies and reagents prior to use.
- Establish a mechanism to review in-use supplies and reagents to ensure they are within documented expiration dates. A random audit of material in-use is recommended.
- Work with supplies to ensure that delivery of orders, especially standing orders, is in a timely manner.
- Ensure that any materials that have a change in expiration date upon opening or removal from storage have been given the “correct” new expiration date as required by manufacturer requirements.

**No. 9. Personnel Education** {WAC 246-338-060(3)(b)(i)}: The MTS director must evaluate, verify, and document the education, experience, and training for all testing personnel. This deficiency will be cited if there is no documentation showing that the testing personnel are qualified to perform laboratory testing.

Compliance Tips:

- Establish a hiring protocol that includes documentation that testing personnel are qualified to perform moderate or high complexity testing.
- Verify that current personnel have documentation on record that they are qualified to perform laboratory testing.
- Establish a protocol to have any foreign language qualification documentation translated into English so that the surveyor will be able to read qualification.
- Foreign transcripts must be reviewed by approved transcript evaluation agency to determine U.S. degree equivalency.

**No. 10a. Procedures** {WAC 246-338-090(1)(a)}: The MTS must have written procedures and policies available in the work area for analytical methods used by the technical personnel

Compliance Tips:

- Define “what” needs to be done in policies and “how” things are done in your procedures.
- Procedures should be written in Clinical Laboratory and Standards Institute (CLSI) format.
- Establish a timeline for annual review of procedures by the laboratory director.

## 2013 Top 10 Deficiencies, cont'd from page 4

- Document the review and approval of procedures by the laboratory director.
- Ensure that current procedures are available for analytical methods.
- Ensure that the most current product insert is available and signed by the MTS director if used as the primary procedure.
- Ensure that the staff adheres to written procedures and policies.
- Establish a mechanism to update procedures when there are changes in equipment or test methodology.
- Remove procedures no longer performed by the laboratory and place them in a file or separate notebook to be retained for two years.

**No. 10b. Preventative Maintenance Activities** {246-338-090(2)(b)}: The MTS must establish criteria for and maintain appropriate documentation of preventative maintenance activities.

### Compliance Tips:

- Review necessary preventative maintenance required by the manufacturer for all instruments and/or methods.
- Establish a schedule for preventative maintenance activities as required by the manufacturer of instruments or methods.
- Review preventative maintenance logs, either electronically or manually, on a regular basis to ensure that preventative maintenance is documented as per manufacturer requirements.
- Document remedial action when preventative maintenance activities are not performed as required by the manufacturer.

**No. 10c. Method/Instrument Validation Moderate Complexity** {WAC 236-338-090(7)(b)(iii)}: Verify the performance characteristics including the reportable range of patient results when introducing a new moderate complexity procedure. It is the laboratory director's responsibility to review and approve the validation information for acceptability in making clinical decisions.

### Compliance Tips:

- Verify the following performance characteristics for new moderate complexity procedures:
  - Accuracy.
  - Precision.
  - Reportable range of patient results.
  - If using the reference range provided by the manufacturer, verify that it is appropriate for the patient population.
- Retain all paperwork for the validation studies after installation of the new instrument or method for the life of the instrument plus two years.
- The laboratory director will verify that the validation meets all requirements and approve the validation. This must be completed prior to patient testing being performed.

LQA asks that each laboratory review the MTS regulations carefully so it can meet the requirements. See the [LQA](#) website for additional information about the MTS licensing program and other resources.

# Individual Quality Control Plans (IQCP)

**Key points:**

- IQCP replaces EQC
- Education and Transition Phase: January 1, 2014 – December 31, 2015
- Becomes effective January 1, 2016
- Laboratories may establish an IQCP, perform CLIA QC default (two levels of external QC each day of patient testing), or follow the manufacturer’s requirements, if more stringent than CLIA default.

Laboratories can find IQCP educational materials at the **CLIA website**.

Look for more IQCP information in future issues of **Elaborations!**

## Calendar of Events

**Training Classes:**

[2014 Northwest Medical Laboratory Symposium](#)

October 1-4                      Portland, OR

[21st Annual Clinical Laboratory Conference](#)

November 10                      Tukwila

[2015 ASCLS-WA Spring Meeting](#)

April 2015                      Olympia

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.

For persons with disabilities, this document is available upon request in other formats. To submit a request, please call 1-800-525-0127 (TTY/TDD) 1-800-833-6388).



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