

2015 The Top 10 Most Frequently Cited Deficiencies

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The Washington State Department of Health, Laboratory Quality Assurance (LQA) team inspected 242 laboratories in 2015 under the Medical Test Site (MTS) licensing program. This article outlines the top 10 deficiencies cited during 2015. The MTS Washington Administrative Code (WAC) citation appears after each item.

No. 1. Personnel Competency Evaluation {WAC 246-338-060(3)(b)(iv)}: The MTS director must evaluate, verify, and document the competency of technical personnel who perform test procedures and report test results.

Compliance Hints:

- Have a written policy defining personnel competency testing for your facility.
- Make sure 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.

No. 2. 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 Hints:

- Write and follow a record retention policy for your facility that meets or exceeds the requirements in Table 070-1.
- Records must be available during onsite inspections. If some records are stored offsite, be prepared to quickly retrieve records the inspector requests.

No. 3. No Remedial Action Taken {WAC 246-338-080(3)}: Document and maintain all remedial action in

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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 [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	

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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 does not take effective action to correct the problem.

Compliance Hints:

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

No. 4. 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 practice.

Compliance Hints:

- 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 per delegation policy) and the testing personnel.
- Rotate PT sample testing among all testing personnel.
- Make sure the PT samples are treated in the same manner as patient samples.
- Document the review of PT or BV results and any remedial action to correct problems including those results that are not graded by the PT company.

No. 5. Lack of Laboratory Director Oversight

{WAC 246-338-060(3)(a)(ii) and WAC 246-338-060(3)(a)(ii)}: The MTS director must establish and approve policies for performing, recording and reporting test results and maintaining an ongoing quality assurance program. This must be in writing and monitored on a regular basis.

Compliance Hints:

- Verify that testing personnel have current procedures and policies available for performing, recording, and reporting of patient test results. Review and approve these policies and procedures.
- Archive retired procedures and policies and maintain for a minimum of two years. The medical test site director should review and approve these policies and procedures.
- Upon opening a new laboratory or changing license type to a moderate- or high complexity laboratory, the laboratory director must develop a quality assurance program that monitors the quality of laboratory test results.
- Upon upgrading or changed test menu, method, or equipment, the laboratory director should review the validation records and the quality assurance program and adjust it according to requirements of the manufacturer or regulations.
- Review the QA program annually to verify that the QA plan meets the MTS regulations and is being followed by the laboratory testing personnel.

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No. 6. Personnel Education and Training {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 or if there is no documentation of initial training for new testing personnel.

Compliance Hints:

- Establish a hiring protocol that includes documentation that testing personnel are qualified to perform moderate or high complexity testing by having on-site copies of diplomas or transcripts with the actual date of graduation.
- Verify that current personnel have documentation on record that they are qualified to perform laboratory testing.
- Establish a protocol to have any qualification documentation that is in a foreign language translated into English so the surveyor will be able to read the qualifications.
- Foreign transcripts must be reviewed by an approved transcript evaluation agency to determine U.S. degree equivalency.
- Develop an initial testing personnel training document and complete that before performing patient testing.

No. 7. 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 and percent humidity when specified by the test method or equipment. Temperature storage and ranges are found in the package insert and/or on the reagent box.

Compliance Hints:

- Establish acceptable temperature ranges. If the manufacturer recommends different ranges, the range used should be the most restrictive.
- 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 an adjustment to the thermostat.
- Make sure thermometers are calibrated and reading accurately.

No. 8. Establish or implement reportable range for moderate complexity testing {WAC 236-338-090(7)(a)(iii)}: The laboratory director is responsible to review and approve validation studies for new equipment or methods for acceptability prior to reporting patient test results.

Compliance Hints:

- Verify the following performance characteristics for new moderate complexity procedures prior to use:
 - Accuracy
 - Precision
 - Reportable range of patient results
 - If using the reference range provided by the manufacturer, verify that it is appropriate for the laboratory's patient population.
- Retain all documentation from the validation studies after installation of the new equipment or test for the life of the instrument plus two years.
- The laboratory director will verify and approve that the validation studies meet all requirements prior to performing patient testing.
- If the reportable range studies are slightly different than the manufacturer's, the laboratory must use the most stringent parameters as the reportable range.

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No. 9. Preventative Maintenance Activities {246-338-090(2)(b)}: The MTS must establish criteria for and maintain appropriate documentation of preventative maintenance activities.

Compliance Hints:

- 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, regularly 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. 10. 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 Hints:

- 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, 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 electronic medical records systems.

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

23rd Annual Clinical Laboratory Conference

What?

The 23rd Annual Clinical
Laboratory Conference

When?

Monday, November 14, 2016

Where?

Foster Links Golf Course
Tukwila, WA

Plan to attend.

Mark your calendars now!!!

Public Health Websites of Interest

Arboviral Disease

<http://www.doh.wa.gov/ForPublicHealthandHealthcareProviders/NotifiableConditions/ArboviralDisease>

Zika Virus

Guidance for Clinical Labs

<http://www.doh.wa.gov/Portals/1/Documents/5100/ZikaGuidanceClinicalLabs.pdf>

Calendar of Events

Training Classes:

2016 ASCLS-WA Spring Meeting

April 14-16 Renton

2016 Northwest Medical Laboratory Symposium

October 12-15 Portland

23rd Annual Clinical Laboratory Conference

November 14, 2016 Tukwila

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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