Washington State Department of Health
ELABORATIONS
News and Issues for Washington's Clinical Laboratories

Volume XXIII Issue 6 November/December 2019

10 Most Frequently Cited Deficiencies in 2018

by Nora Estes, Department of Health/LQA

The Washington State Department of Health, Laboratory Quality Assurance (LQA) team inspected 302 laboratories in 2018 under the medical test site (MTS) licensing program. This article outlines the top 10 deficiencies cited during 2018. The MTS Washington Administrative Code (WAC) citation appears after each item.

No. 1. No Remedial Action Taken {WAC 246-338-080(3)}: Document and maintain 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 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. 2. 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 hints:

• 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.
• 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

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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.

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

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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. 3a. 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 on the left side of the screen about PT requirements and a list of the regulated analytes under the "MTS Proficiency Testing" option. 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. 3b. 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. 4. 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. 5. Equipment Function Checks were not completed as required {WAC 246-338-090(2)(c)}: The laboratory must establish written criteria for, and maintain appropriate documentation for, equipment function checks.

Compliance hints:
• Review all manufacturer product inserts and regulations to identify function checks required by the manufacturer or regulating organizations. Establish a schedule to perform these function checks and record that they have been performed.
• Review schedule for function checks when new tests,
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ELABORATIONS is a free monthly publication of the Washington State Department of Health (DOH) Public Health Laboratories (PHL) and Office of Laboratory Quality Assurance (LQA).

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methods, or equipment are installed and put into use. Follow manufacturer product inserts and regulatory requirements.
• Rotate these function checks among all testing personnel who are responsible for instrument performance.
• Review documentation to validate that equipment functions checks are being performed as required.

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. 7a. Lack of Laboratory Director Oversight {WAC246-338-060(3)(a)(iii) 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.

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• 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.

No. 7b. 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 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. 8a. 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. 8b. Calibration and Calibration Verification {WAC 246-338-090(7)(a)}: Calibration and calibration verification for moderate and high complexity testing as described in Table 090-2.

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Compliance hints:

• Makes sure instrument is calibrated at on-site installation.
• Review manufacturer requirements for frequency of required calibrations.
• Makes sure to perform full calibration whenever calibration verification fails to meet acceptable criteria.
• For calibration verification, make sure reference materials evaluate the lower, mid-point, and upper limits of the procedures reportable range.
• Set calendar reminders for required six-month calibration verifications.
• Perform calibration verification when there is a complete change of reagents, after major preventative maintenance activities, or when controls are outside acceptable limits or trends.

No. 9. Reagent Documentation {WAC 246-338-090(3)(a)(i)}: The medical test site must maintain documentation of reagent expiration dates, lot numbers, and other pertinent information.

Compliance hints:

• Create a log of reagents used by the medical test site and retain per the requirements in Table 070-1.

No. 10a. Policy Approval {WAC 246-338-060(3)(a)(i)}: Medical test site directors must establish and approve policies for performing, recording, and reporting of tests.

Compliance hints:

• Make sure the lab director approves policies in use by the laboratory before the beginning of testing.
• Lab directors must approve any substantive changes to lab polices.
• Lab directors cannot delegate the approval of policies.

No. 10b. Reporting Patients Results {WAC 246-338-090(6)(f)}: Report patient results only when reference materials are within acceptable limits.

Compliance hints:

• Make sure acceptable limits for quality control are established and available to testing personnel before patient testing.
• Quality control must pass before patient testing and reporting.

Thanks to all who made the 26th Annual Clinical Laboratory Conference a Great Success!!!!

Calendar of Events

Training Classes:

2020 ASCLS-WA Spring Meeting
April 23-24 Richland

2020 Northwest Medical Laboratory Symposium
October 14-17 Portland, OR

27th Annual Clinical Laboratory Conference
November 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.

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DOH 505-068 November 2019