Washington State Department of Health
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2011 Top Ten Most Frequently Cited Deficiencies

by Linda Parisi DOH/LQA

The Washington State Department of Health Laboratory Quality Assurance (LQA) team inspected 295 laboratories in 2011 under the Medical Test Site (MTS) licensing program. This article outlines the top ten deficiencies cited in laboratories during 2011. The MTS Washington Administrative Code (WAC) citation appears after each item.

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

Compliance Hints:
- Establish an effective mechanism to recognize that problems exist and document effective corrective action.
- Document, document, and document.

#2 Personnel Competency Evaluation {WAC 246-338-060(3)(b)(iv)}: Medical Test Site directors must evaluate, verify and document the competency of technical personnel to perform test procedures and report test results.

Compliance Hints:
- 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 competency training of new testing personnel, again at six-months, and yearly thereafter.
- Document remedial action for personnel failing the competency assessment.

#3 Procedures {WAC 246-338-090(1)(a)}: The Medical Test Site must have written procedures and policies available in the work area for analytical methods used by the technical personnel.

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

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Compliance Hints:
- Define "what" needs to be done in policies and "how" things are done in your procedures.
- Procedures should be written in CLSI format.
- Establish a timeline for annual review of policies and procedures.
- Document the review and approval of all new procedures by the laboratory director.
- Ensure that current procedures are available for analytical methods.
- Ensure the most current product insert is available.
- Ensure that staff adhere to the written procedures.
- 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.

#4 Method/Instrument Validation Moderate Complexity {WAC 346-338-090(7)(b)}: Verify the performance characteristics 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 Hints: Verify the following performance characteristics for new moderate complexity procedures:
- Accuracy.
- Precision.
- Reportable range of patient test 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/method, verify that the validation meets all requirements and have lab director review and approve the vali dation.

#5 Record Retention {WAC 346-338-070(8)}: The Medical Test Site must retain records, slides, and tissues as described in Table 070-1, under storage conditions that ensure proper preservation.

Compliance Hints:
- Write 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 the records requested by the inspector.

#6 Temperature Records {WAC 346-338-090(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 requirements and ranges are found in the package insert and/or on the reagent box.

Compliance Hints:
- Establish temperature acceptable range.
- Record temperature on each business day.
  - This includes room temperature if specified for reagents, supplies, or equipment.
- Document corrective action taken when temperatures are outside acceptable limits.
- Re-record temperature several hours after any adjustment to thermostat.

#7 Proficiency Testing {WAC 346-338-050(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 alternate method (Biannual Verification) to comply with

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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 Policy for non-regulated analytes; test at least two samples per analyte twice per year.
- Check the attestation statements for the signatures of the director (or designee) and the testing personnel.
- Document the review of PT or Biannual Verification results and any remedial action to correct problems.

#8 Personnel Education, Experience and Training {WAC 346-338-060(3)(b)(i)}: MTS directors must evaluate, verify, and document the following related to technical personnel: education, experience, and training in test performance and reporting test results.

Compliance Hints:
- Establish a policy to confirm education and experience of testing personnel.
- Establish a training program to guarantee testing personnel will perform technical procedures accurately.
- Maintain copies of diplomas or transcripts for high complexity testing personnel.

#9 Director/personnel qualifications/responsibilities {WAC 346-338-060(1)(c)}: MTS owners must meet the standards for personnel and responsibilities in compliance with federal regulation as listed in 42 CFR Part 493 Subpart M - Personnel for Non-waived Testing.

Compliance Hints:
- Write job descriptions for all personnel and verify that all personnel meet the qualifications and are performing the responsibilities for moderate or high complexity testing as defined by federal regulation, listed in 42 CFR Part 493 Subpart M - Personnel for Non-waived Testing.
- Keep documentation of qualifications available for review at the time of inspection.

#10 Calibration/Calibration Verification {WAC 346-338-090(7)(a)}: Calibration and calibration verification is required for moderate and high complexity testing as described in the MTS WAC in Table 090-2. There are exceptions to the Calibration Verification regulation so review that carefully under the "Supplemental Material" option on our website.

Compliance Hints 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 data.
- Retain package insert from the calibration material.

Compliance Hints for Calibration Verification:
- Have a written procedure and schedule defining which methods require calibration verification.
- Perform
  - Every six-months
  - When there is a complete change of reagents (new low number)
  - When controls are outside acceptable limits or exhibit trends
  - When major preventive maintenance is performed or critical instrument parts are replaced.

LQA asks that each laboratory review the MTS regulations carefully so they can meet the requirements. Visit the **LQA website** for additional information about the MTS licensing program and other resources.

MTS/CLIA License Renewal

Medical Test Site (MTS) license renewal fee cards were mailed on March 22, 2013. Contact the LQA Office at 253-395-6746 if you have not received your renewal notice.

The renewal fee payment for MTS licneses is due by June 1, 2013.

Visit the **LQA website** to obtain additional information about the MTS/CLIA license renewal process.

Calendar of Events

Training Classes:

2013 ASCLS-WA Spring Meeting
April 25-27 Lynnwood

2013 Northwest Medical Laboratory Symposium
October 16-19 Lynnwood

20th Annual Clinical Laboratory Conference
November 2013 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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