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2012 Top 10 Most Frequently Cited Deficiencies

by Linda Parisi DOH/LQA

The Washington State Department of Health Laboratory Quality Assurance (LQA) team inspected 288 laboratories in 2012 under the Medical Test Site (MTS) licensing program. This article outlines the top 10 deficiencies cited in laboratories during 2012. The MTS Washington Administrative Code (WAC) citation is listed 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. The deficiency will result from the lack of appropriate documentation. This deficiency is also cited when the laboratory fails to recognize it has a failure and/or does not take an effective action to correct the problem.

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

#2. Expired Reagents {WAC 246-338-090(6)(a)}: The MTS must use materials before their documented expiration date. The deficiency will be cited when supplies are being used beyond their documented expiration date. This may also be cited when supplies requiring a change of expiration date upon opening or removal from storage are not changed or are being used beyond the "new" expiration date.

Compliance Tips:
• Ensure that staff members are aware of the regulation stating that materials must be used before their documented expiration date or new expiration date if changed upon opening or removal from storage.
• Establish a procedure to check expiration dates of supplies prior to use.
• Establish a mechanism to review in-use supplies to ensure they are within documented expiration dates. A random audit of materials in-use is recommended.
• Work with suppliers to ensure delivery of orders is timely.
• Ensure that any materials that have a change in expiration date upon opening or removal of storage have been given the "correct" expiration date as required by manufacturer

continued on page 2

Inside This Issue

2-4 2012 Top 10 Deficiencies, cont'd
4-5 PHL Specimen Mailing Information
6 LQA Staffing Update/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
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

2012 Top 10 Deficiencies, cont'd from page 1

requirements.

#3 Proficiency Testing {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 alternate method (Biannual Verification) to comply with the regulations. PT is not required for waived tests, but is recommended as good laboratory practice.

Compliance Tips:
• 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 signatures of the director (or designee) and the testing personnel.
• Document the review of PT or Biannual Verification results and any remedial action taken to correct problems or failures.

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

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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 competency training of new testing personnel, again at six months, and yearly thereafter.
• Document remedial action taken for personnel failing the competency assessment.

#5. Preventative Maintenance Activities {246-338-090(2)(b)}: The MTS must establish written criteria for and maintain appropriate documentation of preventative maintenance activities.

Compliance Tips:
• Review necessary preventative maintenance required by the manufacture for all instruments and/or methods.
• Establish a schedule for preventative maintenance activities as required by the manufacturer of instruments or methods.
• Regularly review preventative maintenance logs, either electronically or manually to ensure that preventative maintenance is documented as per manufacturer requirements.
• Document remedial action when preventative maintenance activities are not performed as required by manufacturer.

#6. 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 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.

#7. Procedures {WAC 246-228-090(1)(a)}: The MTS must have written procedures and policies available in the work area for analytical methods used by the technical personnel.

continued on page 3

2012 Top 10 Deficiencies, cont'd from page 2

Compliance Tips:
• Define "what" needs to be done in policies and "how" things are done in your procedures.
• Procedures should be written in the Clinical Laboratory and Standards Institute (CLSI) format.
• Establish a timeline for annual review of policies and procedures.
• Document the review and approval of procedures by the laboratory director.
• Ensure that current procedures are available for analytical methods.
• Ensure the most current product insert is available and signed by your director if used as your primary procedure.
• Ensure that staff members adhere to 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.

#8. Method/Instrument Validation Moderate Complexity {WAC 246-338-090(7)(b)(i)-(iv)}: 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 Tips:
• Verify the following performance characteristics for new moderate complexity procedures:
    o Accuracy
    o Precision
    o Reportable range of patient test results
    o 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. Verify that the validation meets all requirements and have the laboratory director review and sign the validation.

#9. Calibration/Calibration Verification {WAC 236-338-090(7)(a)}: Calibration and calibration verification are 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 the **LQA website**.

Compliance Tips for Calibration:
• Perform at installation of new instruments or methods.
• Review manufacturer's literature of 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 Tips for Calibration Verification:
• Have a written procedure and schedule defining which methods require calibration verification.
• Perform
    o Every six months
    o When there is a complete change of reagents (new lot numbers)
    o When controls are outside acceptable limits or exhibit trends
    o When major preventative maintenance is performed or critical instrument parts are replaced.

#10. 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 requires a specific temperature range. Temperature storage and ranges are found in the package insert and/or on the reagent box.

continued on page 4

2012 Top 10 Deficiencies, cont'd from page 3

Compliance Tips:
• Establish temperature acceptable range.
• Record temperatures on each business day.
    o This includes 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 thermostat.

LQA asks that each laboratory review the MTS regulations carefully so it can meet the requirements. The **LQA website** offers more information about the MTS licensing program and other resources.

PHL Specimen Mailing Information

Improved PHL Specimen Mailing Boxes: The Public Health Laboratories Support Services is always striving to ensure the safety of our employees, our customers, and our mail carriers. In June 2013, the PHL upgraded and consolidated two of the four UN3373 Category B specimen shippers. The PHL made the upgrades to ensure all specimen shippers for our customers meet the U.S. Department of Transportation (DOT) and International Air Transport Association (IATA) regulations.

Why is this important? DOT and IATA enforce strict shipping regulations to ensure all potentially infectious specimens are packaged in a manner that reduces the risk of exposure to all mail handlers.

Who's responsible? Shippers are responsible for ensuring their packages meet regulations. Hefty fines could result for shippers if caught out of compliance. The PHL provides UN3373 Category B specimen mailing boxes to help our customers comply with these regulations.

What is available? The PHL now carries three types of UN3373 Category B Biological Substance mailing boxes for transporting specimens.

The **Small Specimen Mailing Box** contains a clear polypropylene container with a red lid inside a white rigid outer box. The container holds three or four specimens. Each specimen must be individually wrapped with absorbent and a biohazard bag to prevent contaminating the inside of the container and the other specimens. Test requisition forms may be secured around the outside of the clear container with a rubber band. The container is then placed in the rigid outer box. Secure the box with packing tape, affix the appropriate labels, and mail to the PHL with appropriate postage. Our optional yellow mailing bags may also be used to ship a group of boxes together as an over-pack.

continued on page 5

PHL Specimen Mailing Information, cont'd from page 4

The **Medium Specimen Mailing Box** contains a 95 kPa bag as the secondary container inside a white rigid outer box. It is approved for shipping a total of 50 ml of specimen according to manufacturer's specifications. Each specimen must be individually wrapped with absorbent and a biohazard bag to prevent contaminating the inside of the kPa bag and the other specimens. The kPa bag is designed with a built-in pocket where the test requisitions may be stored during shipment. Once the specimens are inserted into the kPa bag, seal the bag, place the test requisitions in the kPa pocket, insert the kPa bag into the rigid box, and secure the box with packing tape. Ensure the box is properly labeled for shipping Category B specimens and ship as is or place inside a yellow over-pack bag and apply appropriate postage.

The **Large Styrofoam Specimen Mailing Box** is designed for use by customers who submit a high volume of specimens to the PHL. This large cardboard box contains a Styrofoam cooler and nine clear jars with red lids. Each jar is designed to hold up to nine specimens, which must be individually wrapped in absorbent and a biohazard bag. Once specimens are placed inside the jar(s) and secured, the test requisitions may be wrapped around the jar, secured with a rubber band, and then all nine jars must be placed back in the box to meet shipping regulations. Place the lid on the Styrofoam cooler and secure the outer box with packing tape. Ensure the box is appropriately labeled to ship Category B specimens and apply the necessary postage.

Please contact the PHL Mailroom at (206) 418-5579 for more information or to place an order. The PHL Laboratory Supply Order Form can be found at: http://www.doh.wa.gov/Portals/1/Documents/Pubs/308-003-LaboratorySupplyOrderForm.pdf

LQA Staffing Update

Kathy LaBeau is leaving Laboratory Quality Assurance after 23 years of service. We wish her the best in her future endeavors.

We thank her for her years of service to the people of Washington State and the DOH.

We will be hiring a surveyor for the Medical Test Site program to replace Kathy. The position will be posted on the **Washington State employment website** in August.

Calendar of Events

Training Classes:

2013 Northwest Medical Laboratory Symposium
October 16-19 Lynnwood

20th Annual Clinical Laboratory Conference
November 6 Tukwila

2014 ASCLS-WA Spring Meeting
April 24-26 Spokane

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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