

MTS Licensing Program Receives Federal Exemption Extension

by Susan Walker, MTS Program Manager

Washington's Medical Test Site licensing program has retained a key federal exemption first granted 20 years ago.

In October 1993, the Centers for Medicare & Medicaid Services (CMS) Clinical Laboratory Improvement Amendments (CLIA) program recognized the Medical Test Site (MTS) licensing program as an exempt-state program. Washington became the first state to have its clinical laboratory licensure program judged by CMS as equivalent to CLIA and was granted an exemption. The exemption from CLIA allows Washington to retain the regulatory activity over clinical laboratories, rather than federal regulatory oversight. That makes it more accessible and responsive to local needs. CMS grants exemptions for six-year periods.

In January 2013, the Department of Health (department) applied for an extension of the exempt-state status for the MTS program. This required sending documentation that the MTS law and rules were equivalent to the federal CLIA regulations. The department submitted documentation of its standard operating procedures and a summary of inspection, proficiency testing, and complaint investigation enforcement actions taken over the past six years. The CMS CLIA program Central Office staff performed a two-day site visit in July to review the MTS program documentation and performed an MTS file and record review.

The CMS CLIA program notified the department on September 12, 2013, that the MTS program has been approved for a six-year extension of our state exemption. In fulfilling the requirements for approval under CLIA, we agreed to make minor changes to the Washington Administrative Code (WAC), Chapter 246-338. MTS program staff are working on the WAC revision process that is due to be completed in March 2014.

The department will notify stakeholders of the proposed WAC change as the process moves forward as required by law. The proposed MTS WAC changes will be announced in a future issue of *Elaborations* or through direct e-mail.

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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	

Proficiency Testing for 2014

Proficiency testing (PT), required under Medical Test Site rules WAC-246-338-050, is a source of external quality control. Although labs perform daily internal quality control with their test systems, external quality control provides important interlaboratory comparisons to determine the accuracy and reliability of your testing procedures.

It is time to enroll in PT for 2014. Page five contains a list of the currently approved PT providers. Call the providers for free copies of their 2014 PT brochures or see their websites. Your current PT provider will automatically send you a PT order form and catalog for 2014. Early enrollment guarantees that you will receive samples for the first testing event that occurs between January and March 2014.

- Shop around for prices and test groups.
- In order to cover all tests performed in your laboratory, it may be necessary to enroll in PT with more than one company.

Urine Culture Growth / No Growth Reminder: Does your laboratory perform urine cultures for growth/no growth only and/or colony count only? If so, participation in a five-sample proficiency testing program applies to you.

Failure to participate in PT results in a score of 0 percent for each analyte. This is a failure, and may jeopardize your

ability to continue testing patient specimens.

Information needed to enroll: Complete the 2014 Order Form in the PT brochure with the following information:

- Name (use the name exactly as it appears on your MTS license)
- Address
- CLIA ID number (primary means of identifying your lab)
- MTS license number (see your MTS license)
- Select the appropriate program for your lab (you may have to enroll in several modules and/or companies to cover all analytes)

NOTE: Authorize the PT agency to send copies of your results to the Washington State Department of Health Office of Laboratory Quality Assurance. Do this for each analyte!

Regulated analytes:

- Five-sample modules shipped three times per year are required for all regulated analytes.
- The [LQA website](#) has a listing of the regulated analytes.
- PT participation is required for all non-waived tests for Influenza A and B, and Direct Strep Antigen.
- Some manufacturers of waived test kits include instructions for moderate complexity testing in the same package insert. This allows the laboratory to choose whether it wants to perform the test as a waived test following the

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Website access:

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[Laboratory Quality Assurance](#)
[Public Health Laboratories](#)

TIPS for Proficiency Testing Success

Improve your chances for successful participation in PT:

- **Release results:** Notify the PT provider to send copies of PT results for each analyte to LQA.
- **Handle PT samples like patient samples, but do not** refer them to your reference/main lab for further study. Do **not** run them multiple times.
- **Retain all raw data:** Save data showing the workup of PT samples, instrument printouts, worksheets, and log sheets.
- **Attestation statement:** Keep a copy of the form signed by the director and personnel who tested the samples.
- **Make sure all testing personnel perform PT during the year:**
- **Be timely:** Always be sure to meet the deadline for returning your results.
- **Review your graded results:** Review the graded PT results with your lab director. Document corrective action for scores below 80 percent. Evaluate ungraded results.

Proficiency Testing for 2014, cont'd from page 2

waived test requirements or as a moderate complexity test following these requirements. If the laboratory chooses to perform the test as a moderate complexity test, it must participate in a five-sample PT program three times per year.

Non-regulated analytes: Test all non-waived tests (other than the regulated analytes) using one or a combination of the following:

- A two-sample PT program from one of the proficiency testing providers, or
- Blind samples with known values, or
- Split samples with another lab, or
- Split samples with another instrument or method, or
- Two analysts perform microscopic tests and compare results, or
- Kodachromes of microscopic tests, or
- Correlate patient results with clinical history.

Adding tests during the year:

- Notify our office within 30 days of adding the tests.
- Enroll in PT for regulated analytes before you start testing patient samples.

Discontinuing tests during the year:

- Notify our office within 30 days of discontinuing the tests.

Temporarily discontinuing tests during the year:

- Notify our office within 30 days if you temporarily discontinue a test.
- Use the appropriate action code from your PT provider if you temporarily discontinue a test at the time of a PT challenge.
- When you reinstate the test, notify our office.

LQA website: The [LQA website](#) contains additional information regarding proficiency testing, applications, licensing, practice guidelines, surveys and checklists, MTS rules, and much more.

If you have other questions regarding proficiency testing, contact Leonard Kargacin at (253) 395-6747.

20th Annual Clinical Laboratory Conference

by Leonard Kargacin, Department of Health LQA

The 20th Annual Washington Clinical Laboratory Conference will be held on Wednesday, November 6, 2013, at Foster Links Golf Course in Tukwila. This is an excellent opportunity to hear about the status of health care from a variety of experts.

Jondavid Klipp, president and publisher of Laboratory Economics in Poughkeepsie, New York, is the keynote speaker for the Conference. He is presenting **“The Outlook for the Lab Industry: 2014 and Beyond.”** This presentation provides a detailed analysis of the outlook for the clinical laboratory and pathology markets in 2014 and beyond. It will include a review of reimbursement trends, mergers and acquisitions, molecular diagnostics, and the build toward bundled payments.

Daniel B Jernigan, MD, MPH, is the Deputy Director of the Influenza Division at the National Center for Immunization and Respiratory Diseases at the Centers for Disease Control and Prevention (CDC), in Atlanta. His presentation is titled **“Emerging Infectious Diseases in 2013: H7N9 Influenza, MERS-CoV, and beyond.”** Attendees will learn about recent infectious disease outbreaks, including influenza A H7N9 in China, influenza A H3N2v swine-associated infections in the U.S., MERS-CoV infections in the Middle East, and other emerging infectious disease outbreaks. These outbreaks characterize the epidemic potential of a world that is more crowded and more connected than ever before.

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20th Annual Clinical Laboratory Conference

Bryant T. Karras, MD, is the Chief Infomatics Officer and Meaningful Use Coordinator at the Washington State Department of Health. His presentation is titled “**Electronic Laboratory Reporting for Meaningful Use Stage 2 – What Labs Need to Know.**” The speaker will provide an overview of Washington’s Medicaid and Medicare EHR Meaningful Use multi-million dollar incentive and what role labs play. He’ll present a detailed explanation of the six-step process for on-boarding of Electronic Laboratory Reporting (ELR) HL7 messages and where to download more information. He’ll also describe a resource that can help labs be ready for the LOINC and SNO-MED codes required for standardized reporting.

Daniel Lessler, MD, MHA, is the Chief Medical Officer of the Washington State Health Care Authority in Olympia. His presentation is titled “**Implementing the Affordable Care Act – Washington’s Approach.**” The speaker will provide a brief history of the Affordable Care Act (ACA) and will describe the Law’s key elements. He’ll provide a detailed explanation of Medicaid Expansion and the “Exchange” in Washington State.

Sue Grinnell, MPH, is the Special Assistant, Health Reform and Innovation, at the Washington State Department of Health. Her presentation is titled “**Health System Reform.**” The speaker will discuss the Affordable Care Act and the roles of the lead state agencies in health reform implementation in Washington. The presentation will increase the participant’s understanding of the Triple Aim (improving the individual experience of care; improving the health of populations; and reducing the per capita costs of care for populations), and the Department of Health’s role.

Brett Cain, MPA, is the program manager responsible for implementing of the Medical Assistants Law for the Washington State Department of Health. His presentation is titled “**Washington State Medical Assistants Law.**” The speaker will discuss the major parts of the medical assistants law and rules that were effective July 1, 2013, briefly review the scope of practice of medical assistants, and provide information on who to reach if there are questions or concerns regarding the new law. There will be time for questions and answers.

Who Should Attend?

- Laboratory directors
- Laboratory / Office managers
- Department supervisors
- Bench personnel
- Billing personnel
- Compliance officers

The Conference offers something pertinent for everyone whether you work in a physician office laboratory, an independent laboratory, or a small or large hospital.

Location

The Conference is held at the Foster Links Golf Course with easy access from Interstate 5 and the airport. See the [Laboratory Quality Assurance](#) website under “Updates” on the left of the screen for information and a registration form for the 2013 Conference or contact [Leonard Kargacin](#). The \$95 per-person registration fee includes a continental breakfast, breaks and lunch. Make your plans today to attend. You still have time to register.

Approved PT Providers

[Amer. Acad. of Family Physicians](#) (800) 274-7911

[Amer. Assoc. of Bioanalysts](#) (800) 234-5315

[American Proficiency Institute](#) (800) 333-0958

[ASIM Medical Lab Evaluation](#) (800) 338-2746

[California Thoracic Society](#) (714) 730-1944

[College of American Pathologists/EXCEL](#)
(800) 323-4040

[WSLH](#) (800) 462-5261

For answers to your PT questions, go to the [LQA website](#) or call Leonard Kargacin at (253) 395-6747.

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.

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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