Washington State Department of Health

ELABORATIONS

News and Issues for Washington's Clinical Laboratories

Volume XIX Issue 2 March/April 2014

Medical Test Site Rule Changes

by Susan Walker, DOH MTS Program Manager

The Department of Health's (department) Laboratory Quality Assurance (LQA) program has officially adopted amendments to WAC 246-338-070—Records for Medical Test Sites rules, which include additions to record retention requirements for blood/blood components and individual products, and updates the histopathology report record-keeping requirements. The **CR-103 rule making documents** and revised rules were filed with the Code Reviser's Office on April 2, 2014, WSR # 14-09-001. The revised rules will become effective 31 days after the filing date or May 3, 2014.

This adopted rule amendment is in response to the Centers for Medicare and Medicaid Services' (CMS) 2013 state exemption audit findings for the department's Medical Test Site (MTS) Program. The CMS audit was part of their periodic review of states that have an exempt status under the Clinical Laboratory Improvement Amendments (CLIA).

The department wants to ensure compliance with federal regulations to maintain its exemption status from CLIA regulations. The adopted, amended WAC 246-338-070 is in direct response to the CMS audit findings related to 21 CFR 606.160(b)(3)(ii), (b)(3)(v), and (7)(d) regarding records retention for blood and blood components, and individual product records. In addition, CMS' audit findings specified the department must update its histopathology report record-keeping rule to be in compliance with CLIA guidelines and 42 CFR 493.1273(d) and (e). The CMS audit team approved the adopted amended rule as appropriate steps for the department to take in order to come into compliance with federal regulations and CLIA guidelines. The changes to the MTS regulations are listed below in red and will be effective on May 3, 2014. For more information about the adopted amendments, please contact Susan Walker, Manager, Laboratory Quality Assurance/Medical Test Sites at susan.walker@doh.wa.gov or (253) 395-6745.

WAC 246-338-070 RECORDS
Medical test sites must maintain records as described in this section.

(5) HISTOPATHOLOGY REPORTS must include the signature or initials of the technical supervisor or an electronic signature authorized by the technical supervisor on

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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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Red Cell Transfusion
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Urinalysis
Wellness

Elevated Blood Lead - Updated Definition

by Rad Cunningham, DOH Environmental Public Health Division

On March 12, the Washington State Board of Health voted unanimously to change the definition of elevated blood lead level in the notifiable conditions rule (WAC 246-101). The new rule sets the definition of elevated blood lead (WAC 246-404-010) at 5 µg/dL for children under age 15 and 10 µg/dL for adults. The change aligns lead levels in the notifiable conditions rule with guidance issued by the Centers for Disease Control and Prevention (CDC) on elevated blood lead levels for both children and adults.

Laboratoriess must report all blood lead results to the Washington State Department of Health under the notifiable condition rule. Blood lead levels of 5 ug/dL and higher in children and 10 ug/dL or higher in adults must be reported within two business days, and non-elevated results within 30 days. The new rule allows state and county health departments to respond to lead-poisoned children faster and help the Department of Labor and Industries conduct higher-quality workplace investigations.

Although the rule will not take effect until May 19, you can find updates on the **department website.**

Many healthcare providers rely on the guidance printed on the laboratory results form when communicating blood lead results to patients. Laboratories should update this guidance to reflect changes in state and national definitions of elevated blood lead level. If you have any questions about the rule change or about lead reporting, please contact **Rad Cunningham**.

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Department of Health
Laboratory Quality Assurance
Public Health Laboratories

New LQA Surveyor

Laboratory Quality Assurance has hired a new laboratory surveyor, Veronica Bush, to replace Kathy LaBeau. who retired last July. Veronica has worked in clinical laboratories for more than 21 years. As a member of the U.S. Army and the U.S. Public Health Service, she has experience working in a variety of laboratory settings, ranging from small clinics and physicians' offices to large medical center laboratories.

Before moving to Washington, she was an instructor-writer for the Academy of Health Sciences with special emphasis in laboratory management and Hematology. Veronica has served in supervisory roles as well as managing a remote laboratory in the Balkans. Throughout her career she has worked in all of the primary disciplines in the clinical laboratory.

She earned her bachelor's degree in Medical Technology from Wayland University and her masters in Public Health from Walden University. Her professional certifications are held with the American Society of Clinical Pathology (ASCP) and the American Medical Technologist (AMT). One of Veronica's primary professional goals is to provide sound technical assistance and education to laboratory professionals across the state to ensure that all Washingtonians receive the best possible health outcomes from their diagnostic laboratory testing.

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all reports. Reports must be signed by the same qualified individual who performs the diagnostic interpretation and evaluation and must utilize appropriate terminology such as the SnoMed system.

(8) The medical test site must retain records, slides, and tissues as described in Table 070-1, under storage conditions that ensure proper preservation.

Table 070-1 Record/Slide/Tissue Retention Schedule

		Two Years	Five Years	Ten Years
(a)	General Requirements for all Laboratory Specialties	• Test requisitions or equivalent; • Test records, including instrument printouts if applicable; • Test reports; • Quality control records; • Quality assurance records; • Proficiency testing records; • Hard copy of report, or ability to reproduce a copy, for all specimens referred for testing; and • Discontinued procedures for all specialty areas		
(b)	Transfusion Services		• Test requisitions or equivalent; • Test records; • Test reports; • Quality control records; and • Quality assurance records	• **Individual Product Records***
(c)	Cytology		• All cytology slides, from date of examination of the slide	• All cytology reports
(d)	Histopathology/Oral Pathology	• Specimen blocks, from date of examination		• All histopathology and oral pathology reports; and • Stained slides, from date of examination of the slide
(e)	Histopathology/Oral Pathology-Tissues	Retain remnants of tissue specimens in an appropriate preserved state until the portions submitted for microscopic examination have been examined and diagnosed		
(f)	Instrument/method Validation Studies	For life of instrument/method plus two years		

*Must be retained for no less than ten years in accordance with 21 C.F.R. 606.160(7)(d).

MTS/CLIA License Changes?

Do you want to make changes to your current MTS/CLIA license? There are forms available on the **Laboratory Quality Assurance website** to facilitate the process.

Test Menu Change Form: Use this form to
- add tests to your laboratory test menu
- delete tests from your laboratory test menu

Credential Status Change Form: Use this form to update:
- facility name, address, phone #, and fax #
- laboratory Contact and/or e-mail address
- laboratory Director and/or e-mail address

Can't find what you are looking for or have qustions? Contact **Leonard Kargacin**.

Calendar of Events

Training Classes:

2014 ASCLS-WA Spring Meeting
April 24-26 Spokane

2014 Northwest Medical Laboratory Symposium
October 1-4 Portland, OR

21st Annual Clinical Laboratory Conference
November 10 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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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).