

## 2011 MTS License Renewal

by Susan Walker, DOH/LQA

Current Medical Test Site (MTS) licenses expire on June 30, 2011. The MTS rules require licensees to submit the license renewal fee a minimum of 30 days prior to the expiration date of the license.

### 2011 MTS License Renewal Process for ALL Laboratories:

- We will mail a **Notice to Renew** fee statement for the two-year relicensing period to your facility on April 1.
- Review and update the pre-printed information on **both** sides of the **Notice to Renew** fee statement. See below for a description of the pre-printed information found on the statement.
- Return your updated **Notice to Renew** fee statement with your payment to the address on the form.
- We will send your updated license to the **mailing address** shown on the bottom left of the front of the **Notice to Renew** fee statement.

### Contact the LQA Office at (206) 418-5600 if:

- You need to change your license type
  - o You now perform PPMP testing and you currently have a Certificate of Waiver license.
  - o You now perform only waived tests and you currently have a PPMP license.
  - o You perform tests not classified as waived or PPMP. Go to the [LQA website](#) for a current list of waived and PPMP tests. Select MTS Laws.
  - o You no longer perform any moderate or high complexity testing. MTSC or MTSA.
  - o Your accreditation status has changed. MTSC or MTSA.

- You no longer need an MTS license. You no longer perform any PPMP, waived, moderate, or high complexity testing; you retired, the office closed, etc.

**Pre-Printed Information found on Notice to Renew fee statement:** Make sure you check the information pre-printed on the form for accuracy. The information on the Notice to Renew fee statement is entered into the MTS computer system and the Centers for Medicare & Medicaid Services (CMS) computer system. The information in the CMS database is accessed by government reimbursement agencies, such as Medicare and Medicaid, who use the information to reimburse provider medical claims. Inaccurate information may jeopardize your reimbursement for laboratory testing from Medicare and Medicaid.

Pre-printed information from the front side of the **Notice**

continued on page 3

### Practice Guidelines

The following practice guidelines have been developed by the Clinical Laboratory Advisory Council. They can be accessed at the following website:  
[www.doh.wa.gov/lqa.htm](http://www.doh.wa.gov/lqa.htm)

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	

### Inside This Issue

2-3	FDA: Reporting Device Related Adverse Events
3	2011 MTS License Renewal, cont'd
4	WA PHL External Training Program Closing
4	Calendar of Events

# FDA: Reporting Device-Related Adverse Events

by Linda Parisi, DOH/LQA

An important part of the Food and Drug Administration (FDA) program for regulation of medical devices is surveillance of problems after an FDA approved device enters the marketplace. It assures safety and timely identification of problems.

When the FDA identifies problems, it works with manufacturers to take necessary action to protect the public health. To address the problems, it uses educational tools such as publications, public health notices, workshops, joint communications with CDC -- MMWR reports, and enforcement tools such as recalls, directed inspections, and labeling changes.

**Required reporting of adverse events that result in serious patient injury or death:** The FDA requires manufacturers, importers, and health care professionals in hospitals and outpatient diagnostic facilities to report the event.

- **Death:** File the report with both the FDA and the device manufacturer.
- **Serious patient injury:** File the report with the manufacturer only, unless the manufacturer is unknown. If the manufacturer is unknown, file it with the FDA.\*

- File FDA [Form 3500A](#) or an electronic equivalent no later than ten working days from the time personnel become aware of the event.

**\*Note:** The Washington State Department of Health requires certain facilities to also report adverse events to its [Adverse Event Reporting](#) program including those related to devices.

**The FDA defines serious patient injury as one that**

- is life threatening; or
- results in permanent impairment of a body function or permanent damage to a body structure; or
- necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.

**Note:** Inaccurate test results produced by an In-Vitro Diagnostic Device (IVD) and reported to the health care professional may lead to medical situations that fall under the definition of serious injury. -These are reportable events.

**Voluntary reporting of other adverse events:** The FDA requires manufacturers to report when a device fails to perform as intended and there is a chance of death or serious injury because there may be a recurrence of the malfunction. The FDA encourages health care professionals in hospitals and outpatient diagnostic facilities to:

- report device malfunctions to manufacturers. Malfunctions may relate to any aspect of a test including hardware, labeling, reagents, calibration, or user error that may be related to faulty instrument instructions or design.
- submit voluntary reports of device malfunctions and patient injuries that do not qualify as serious injuries by using FDA [Form 3500](#).
- submit voluntary reports of adverse events noted in the course of clinical care, not events that occur in the course of clinical trial or other studies. You can find [instructions](#) on how to submit a voluntary report on the FDA website.

**Laboratory policies:** The clinical laboratory should have written procedures for

- the identification and evaluation of adverse patient events,

*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).

Secretary, DOH: Mary Selecky  
 Health Officer: Maxine Hayes, MD, MPH  
 Director, PHL: Romesh Gautam, PhD  
 Program Manager, LQA: Susan Walker  
 Editor: Leonard Kargacin (206) 418-5416  
 Circulation: Leonard Kargacin (206) 418-5416

Comments, letters to the editor, information for publication, and requests for subscription can be directed to:  
*ELABORATIONS*  
 Washington State Public Health Labs  
 1610 NE 150th Street  
 Shoreline, WA 98155

e-mail address: [leonard.kargacin@doh.wa.gov](mailto:leonard.kargacin@doh.wa.gov)

NOTE: Letters to the editor may be published unless specified otherwise by the author.

**Website addresses:**  
[DOH home page](#)  
[LQA home page](#)  
[PHL home page](#)

continued on page 3

## 2011 MTS License Renewal, cont'd from page 1

### to Renew fee statement:

- MTS License Type and Number
  - MTSW (Certificate of Waiver)
  - MTSP (Provider Performed Microscopic Procedures)
  - MTSC (Categorized – inspected by Laboratory Quality Assurance staff)
  - MTSA (Accredited – inspected by accreditation agency staff)
- **Name of Facility:** The name listed should be the name you routinely use to identify your facility.
- **Address Information:**
  - **Mailing Address** (lower left of card)
  - **Site Address:** This is the physical location of the facility.
- Telephone Number: Be sure the area code and phone number are correct.
- Fax Number: Add the fax number if it is not listed.

### Pre-printed information from the reverse side of the Notice to Renew fee statement:

- **Owner Federal Tax ID Number (EIN):** This should be the number used for tax reporting purposes. When a facility originally applies to an insurance company to for reimbursement eligibility, the insurance company requires a Tax ID Number.
- **Owner Name:** The name of the owner registered with the Washington State Departments of Revenue or Secretary of State.
- **Personnel:** Verify or add the information for the following categories
  - Lab Director: director of the laboratory. If there is a new director, complete the “Change in Director” form found under the “Supplemental Material” listing on the LQA website (<http://www.doh.wa.gov/lqa.htm>).
  - Lab Contact: full name of the person we can contact to verify information about the facility, to schedule on-site inspections, and discuss problems.
  - Microbiology Contact: supervisor of the microbiology department.
- **E-Mail Address:** Please list an e-mail address, if available, for the personnel categories listed above.

### Questions?

Please call us at (206) 418-5600 us with any questions you have on the license renewal process or completing the renewal application form. It is better to call than provide incorrect information.

## FDA: Reporting Adverse Events, cont'd from page 2

- the timely submission of required medical device reports, and
- compliance with record keeping requirements.

Find more information on [laboratory policies](#) on the FDA website.

### Laboratories that are part of a larger organization (e.g., hospital laboratories) should:

- document participation in the overall institutional Medical Device Reporting (MDR) process.
- educate its personnel in the FDA MDR requirements.
- submit an annual report of device-related deaths and serious injuries to FDA if any such event was reported during the previous year. Annual reports must be submitted on FDA [Form 3419](#) or an electronic equivalent by January 1 of each year. The laboratory or institution must keep records of MDR reports for two years.

