

# ELABORATIONS

News and Issues for Washington's Clinical Laboratories

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## 21st Annual Clinical Laboratory Conference

The 21st Annual Clinical Laboratory Conference will be held on November 10, 2014, at the Foster Links Golf Course in Tukwila. This is an excellent opportunity to hear about the status of health-care from a variety of experts.

**Ebola Virus Outbreak Update:** Marisa A. D'Angeli, MD, MPH, medical epidemiologist from the Washington State Department of Health, will speak about the Ebola outbreak in West Africa, and safety and preparedness for Ebola in the United States and in Washington.

**Dennis Weissman**, president of Dennis Weissman & Associates, LLC, in Washington, DC, is the keynote speaker for the Conference. He is presenting "Changing State of the Lab Industry: Getting Ready for an Historic Turning Point." The clinical laboratory industry is being buffeted by unrelenting market pressures revolving around continuing payment cuts, restrictive coverage and coding policies by both government and private health plans along with expanding value-driven health care reforms. Weissman will address recent statutory and administrative initiatives affecting Medicare payment and coverage for clinical laboratory and pathology services and their implications for the industry. The speaker will identify key political and market trends affecting labs and pathologists, and will discuss federal policies aimed at patient access to lab test results, oversight of lab-developed tests and changes covering local coverage determinations for lab tests.

**Jim Gallarda, PhD**, is the Senior Program Officer in Integrated Development Diagnostics at the Bill and Me-

linda Gates Foundation in Seattle. He is presenting "Gates Foundation Investments in TB Diagnostics for Developing Countries and the Potential Impact in Developed Countries." This talk will focus on the current strategic priorities the Foundation has for TB diagnostics and the challenges of delivering effective solutions in the developing world. The speaker will discuss the Foundation's diagnostic strategies, lessons learned with the launch of the Cepheid Xpert MTB/RIF TB diagnostic assay, and the broader "ecosystem" challenges to IVD companies developing TB diagnostics for the developing world.

**Tera Eerkes, PhD**, is the Director of Research and Development for Iverson Genetics in Seattle. She is presenting "The Bleeding Edge: The Impact of New Molecular Diagnostic Technologies in High-Complexity Testing Laboratories and Laboratory-Developed Tests." The speaker will review recent changes in molecular diagnostics technology and methodologies, and then elaborate on the potential advantages and challenges of adoption of those technolo-

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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	

# 21st Annual Clinical Lab Conference, cont'd from page 1

gies in clinical testing environments. The presentation will review molecular diagnostics using digital PCR methods, Next-Generation Sequencing methods, and Multiplexed or other array-based methods; discuss the advantages and challenges of implementing each of these technologies in a clinical lab setting; and discuss future developments and technologies on the horizon and possible regulatory changes that may affect LDTs using these technologies.

**Lori Eschenbacher, BSMT (ASCP)**, is the Department of Health Laboratory Surveyor for the Medical Test Site licensing program office in Eastern Washington. She is presenting "Individualized Quality Control Plan (IQCP)."

The Centers for Medicare and Medicaid Services (CMS) is implementing a new quality control option based on risk management called the individualized quality control plan (IQCP). Effective January 1, 2016, Equivalent Quality Control (EQC) will no longer be an acceptable option for QC. Laboratories using EQC must consider which QC option (two levels of control daily or IQCP) they will use after the effective date. The speaker will provide an overview of the key components of an IQCP (risk assessment, quality control plan, and quality assessment), and discuss implementation strategies.

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Secretary, DOH: John Weisman, DrPH, MPH  
Health Officer: Kathy Lofy, MD  
Director, PHL: Romesh Gautam, PhD  
Program Manager, LQA: Susan Walker  
Editor: Leonard Kargacin (253) 395-6747  
Circulation: Leonard Kargacin (253) 395-6747

Comments, letters to the editor, information for publication, and requests for subscription can be directed to:

*ELABORATIONS*  
Laboratory Quality Assurance  
20425 72nd Ave S Ste 310  
Kent, WA 98032

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 access:**

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

**Who should attend?**

- Laboratory directors
- Laboratory and 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](#) (click on "Updates" on the right of the screen) for information and a registration form for the 2014 Conference or contact Leonard Kargacin at [leonard.kargacin@doh.wa.gov](mailto:leonard.kargacin@doh.wa.gov). The \$95 per person registration fee includes a continental breakfast, breaks and lunch. Make your plans to attend today. You still have time to register.

## FDA: Reporting Device-Related Adverse Events

by Linda Parisi, Department of Health/LQA

An important part of the Food and Drug Administration (FDA) program for regulation of medical devices is surveillance of problems with FDA-approved devices after they enter the marketplace. The FDA surveillance process ensures safety and timely identification of problems.

When the FDA identifies problems, it works with manufacturers to take necessary action to protect the public's health. Examples of FDA actions include 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 adverse event as follows:

- **Death:** File the report with both the FDA and the device manufacturer.

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

- **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 10 working days from the time personnel become aware of the event.

\*Note: The Washington State Department of Health requires certain facilities to report certain 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 adverse 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 3500A**.
- 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,
- the timely submission of required medical device reports, and
- compliance with record keeping requirements.

**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.

## Mycobacteriology Molecular Methods Course

The Washington State Department of Health Public Health Laboratories will host the **Mycobacteriology Molecular Methods** course at our laboratory in Shoreline, WA on December 5, 2014. This course is sponsored by the National Laboratory Training Network and is presented in our laboratory with the collaboration of Association of Public Health Laboratories (APHL) and the Centers for Disease Control and Prevention (CDC).

The **flyer** contains a course description and relevant details. Potential attendees are required to submit a Survey Monkey application for consideration. The application is hyperlinked in the flyer under the “APPLICATION” section. The course is open to clinical, commercial, and public health laboratorians.

Contact **Ailyn Pérez-Osorio, Ph.D.** if you have any questions.

# Washington's Laboratory Complaint Process

by Susan Walker, Department of Health/LQA

The Laboratory Quality Assurance (LQA) office investigates all relevant complaints concerning laboratories licensed under the Medical Test Site (MTS) law. The office doesn't investigate complaints about OSHA/WISHA concerns, or billing issues. It also doesn't investigate complaints against healthcare professionals, but the filing process is the same with access to the form through the [Washington State Department of Health](#) website.

LQA asks that complaints be put in writing outlining the specific details of the issue(s). We don't require the complainant's identity. Washington State has a whistleblower law to protect employees who file complaints. If the complainant prefers anonymity, we won't record names or identifying information, but the investigation may not be as successful.

**How to file a complaint:** Use these contact options to file a complaint about a laboratory, hospital, pharmacy, other licensed facility, or licensed professionals.

Complaint Hotline:	1-800-633-6828, available 24 hours a day, seven days a week
Phone:	360-236-4700
Fax:	360-236-2626
E-mail:	HSQAComplaintIntake@doh.wa.gov
Mail:	Complaint Intake PO Box 47857 Olympia, WA 98504-7857

The complaint process information and forms are on the [Washington State Department of Health](#) website. See "For health facility complaint information and forms."

A link to the Complaint Process is on the [LQA website](#). Select the "Complaints" option on the right of the screen under Useful Links. Select the "For Health Facility complaint information and forms" option on the next screen.

You may also file a complaint by printing and completing the Complaint Form (see above for information on how to access the form). Mail to:

Complaint Intake  
P.O. Box 47857  
Olympia, WA 98504-7857

**What happens next?** Once we process the initial complaint, it goes to the specific office responsible for inspecting that type of facility. An acknowledgement letter also goes to the person filing the complaint. This letter contains a case number to use when communicating with our office about the complaint.

We evaluate and prioritize every complaint by its potential effect on consumers, residents, or patient health and safety. If we conduct an investigation, it may include an on-site unscheduled visit, interviews, and records review. When the investigation is complete, we send a letter to the person filing the complaint. State regulations do not allow the release of the investigation materials until the investigation is complete.

## Ebola Websites of Interest

The Washington State Department of Health's **Ebola Resources** for Public Health Partners and Healthcare Professionals website has up-to-date information and website links for the latest information about the Ebola outbreak. Visit the site often as updates occur frequently as conditions change.

### Calendar of Events

**Training Classes:**

[21st Annual Clinical Laboratory Conference](#)

November 10                      Tukwila

[2015 ASCLS-WA Spring Meeting](#)

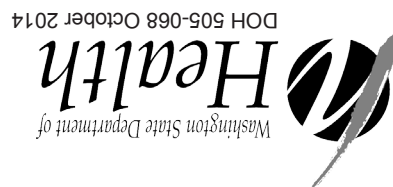
April 23-25, 2015              Olympia

[2015 Northwest Medical Laboratory Symposium](#)

October 14-17, 2015          Seattle

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).



**ELABORATIONS**  
Washington State Department of Health  
20425 72nd Ave S Ste 310  
Kent, WA 98032