Washington State Department of Health
ELABORATIONS
News and Issues for Washington's Clinical Laboratories

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IQCP and Commercial Microbiology Identification Systems

by Susan Walker Department of Health/LQA

The Centers for Medicare and Medicaid Services (CMS) is implementing a new voluntary quality control model based on risk management called Individualized Quality Control Plan (IQCP) that is to be used for tests and test systems that do not follow CLIA/MTS default quality control (QC) requirements. IQCP will provide laboratories with flexibility in customizing quality control policies and procedures based on the test systems in use and the unique aspects of each laboratory.

Effective January 1, 2016, laboratories that use a modification of QC such as streamlined identification (ID) QC for commercial microbiology systems will need to write an IQCP to continue performing streamlined QC. The Clinical and Laboratory Standards Institute (CLSI) recently published the M52 Standard that requires that an IQCP be written if the laboratory is performing streamlined QC with their commercial microbiology system. The lab's verification study or historical review of comprehensive QC results can be used to write the IQCP.

An IQCP consists of three components, risk assessment (RA), quality control plan (QCP) and quality assessment (QA). The RA must cover all three phases of testing (pre-analytic, analytic, and post-analytic) and must include five components (specimen, environment, reagent, test systems, and testing personnel). Historical data such as the data from the laboratory's 20 to 30 day study can be used in the RA. Re-evaluation of the RA must be considered by the laboratory director when any changes are made to the ID system. If the laboratory decides not to perform an IQCP, the laboratory will be required to perform positive and negative reactivity of each reagent or substrate with each new lot and shipment of the ID system. QC strains are easily available from culture collections or commercial sources to test for positive and negative reactivity of each reagent and substrate.

IQCP goes into effect, January 1, 2016. If the laboratory is performing QC less than the CLIA/MTS default QC and does not implement an IQCP, the laboratory will receive a deficiency at its next MTS inspection. For further information refer to "Developing an IQCP; A Step-By-Step Guide" available online through the CDC's website or call your LQA surveyor.

Inside This Issue

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

FDA: Reporting Device-Related Adverses Events

by Linda Parisi, Department of Health/LQA

An important part of the Food and Drug Administration (FDA) program for regulating 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.
• 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.

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Website access:
Department of Health
Laboratory Quality Assurance
Public Health Laboratories

• 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.

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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 P.O. 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.

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

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.

Proficiency Testing Enrollment for 2016

It is time to enroll in Proficiency Testing (PT) for 2016, Visit the Proficiency Testing home page on the Laboratory Quality Assurance website for information about which laboratories must enroll in PT and which laboratory testing needs to be covered by PT. A listing CMS-CLIA Approved Providers is also found at this site.

Calendar of Events

Training Classes:

2016 ASCLS-WA Spring Meeting
April 14 - 16, 2016 Renton

2016 Northwest Medical Laboratory Symposium
October 14 - 17 Portland, OR

23rd Annual Clinical Laboratory Conference
November 2016 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).