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

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# FDA: Reporting Device-Related Adverse Events

by Department of Health/Laboratory Quality Assurance

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 events 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.
- 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 Events 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 malfunc-

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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
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 Adverse Events

tion. 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. Instructions on how to submit a voluntary report are 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 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.

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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**

27th Annual Clinical Laboratory Conference

November 9, 2020

Mark Your Calendars Now!!!!!!

## Calendar of Events

**Training Classes:**

**2020 ASCLS-WA Spring Meeting**
April 23-24 **Cancelled** Richland

**2020 Northwest Medical Laboratory Symposium**
October 14-17 Portland, OR

**27th Annual Clinical Laboratory Conference**
November 9 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.

Washington State Department of Health

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