



COLA PATIENT SAFETY PROGRAM 2012:

FDA voluntary reporting of device-related adverse events

COLA began the COLA Patient Safety Program in 2008 with the intent of focusing on areas in laboratory medicine that are found to have high error rates and significant impact on patient safety. COLA is also focused on reducing the frequency of citations for criteria that impact, or have the potential to impact, patient safety. Through this program, COLA will identify an existing COLA criterion as the patient safety goal for each year, and provide education on good laboratory practices for implementation of that goal. The program has also been integrated into the COLA survey process.

The COLA Patient Safety Goal for 2012 addresses:

ORG 9: Does the laboratory have a procedure for the FDA voluntary reporting of device-related adverse events?

Previous Patient Safety Goals have included proper patient identification, and proper specimen identification and labeling that continues throughout the path of workflow – all of which are essential parts of a safe testing process. But what happens when a testing device malfunctions and either causes, or has the potential to cause, harm?

Every laboratory should have a procedure for voluntary reporting of device related adverse events to the FDA. Lack of a procedure is a common deficiency seen during lab surveys.

A medical device is any item that is used for the diagnosis, treatment, or prevention of a disease, injury, or other condition, that is not a drug or biologic. Consequently, the definition includes devices that may be used in medical laboratories such as instruments, reagents, blood collection devices, and other components of test kits.

Although voluntary, the laboratory has a responsibility to protect the safety of patients and

employees by reporting in-vitro diagnostic devices that do not perform correctly to the manufacturer.

- Inaccurate test results produced by an in-vitro device (IVD) and reported to the health care professional may lead to medical situations that fall under the definition of serious injury, and therefore are reportable events.
- Device malfunctions or problems that are reportable may relate to any aspect of a test, including hardware, calibration, reagents, or labeling; or to user error.
- Device related adverse events can cause serious employee or patient injuries that are life threatening; or result in permanent impairment of a body function or permanent damage to a body structure.

The laboratory should have written procedures for 1) the identification and evaluation of adverse events that effect employees or patients, 2) the timely submission of required medical device reports, and 3) compliance with record keeping requirements.

The COLA website has a resource regarding voluntary FDA reporting at:

www.cola.org/?page_id=417.

There are additional resources on COLAcentral.

More information can be found on the FDA website:

www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm and

www.fda.gov/Safety/MedWatch/ucm133050.htm

Laboratories that are part of a larger organization (e.g., hospital laboratories) should document participation in the overall institutional Medical Device Reporting (MDR) process.

