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Reporting Device-Related Adverse Events to the FDA

Background: An important part of the Food and Drug Administration (FDA) program for regulation of medical devices is surveillance of problems after entry of the device into the marketplace. Surveillance is performed to assure safety and timely identification of performance problems. When problems are identified, FDA works with manufacturers to take necessary action to protect the public health. A cadre of analysts reviews incoming adverse event reporting data. Based on information obtained from these reports the agency may use a variety of educational (publications, public health notices, workshops, and joint communications with CDC - MMWR reports) and enforcement tools (recalls, directed inspections, and labeling changes) to address the problems.

When information reasonably suggests that a laboratory product has or may have caused or contributed to a patient death or serious patient injury, the FDA requires manufacturers, importers, health care professionals in hospitals and outpatient diagnostic facilities, including independent laboratories, to report the event. If the event is death, the report must be made both to FDA and to the device manufacturer. If the event is serious patient injury, the report may be made to the manufacturer only, unless the manufacturer is unknown, in which case the report must be submitted to FDA. Reports must be submitted on FDA Form 3500A (go to FDA forms) or an electronic equivalent as soon as practicable, but, no later than 10 working days from the time personnel become aware of the event.

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. Inaccurate test results produced by an IVD and reported to the health care professional may lead to medical situations that fall under the definition of serious injury as described above, and therefore are reportable events.

FDA requires manufacturers to report device malfunctions when a device fails to perform as intended and the chance of death or serious injury as a result of a recurrence of the malfunction is not remote. FDA encourages health care professionals in hospitals and outpatient diagnostic facilities, including independent laboratories to report such malfunctions to manufacturers. Device malfunctions or problems that are reportable may relate to any aspect of a test, including hardware, labeling, reagents or calibration; or to user error (since the latter may be related to faulty instrument instructions or design).

Health care professionals in hospitals and outpatient diagnostic facilities, including independent laboratories are also encouraged to submit voluntary reports of device malfunctions and patient injuries that do not qualify as serious injuries by using FDA Form 3500.

LabFlorida has written procedures for 1) the identification and evaluation of adverse patient events, 2) the timely submission of required medical device reports, and 3) 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.

LabFlorida educates its personnel in the FDA MDR requirements.

LabFlorida must 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 Form 3419 or an electronic equivalent) by January 1 of each year. The laboratory must keep records of MDR reports for 2 years.

Amendments to the MDR Regulation to Implement FDAMA Changes

To Submit a Voluntary Report

Background: FDA has a procedure for medical personnel to voluntarily report device-related adverse events that may be related to a laboratory test and do not fall under FDA required reporting. This procedure applies to adverse events noted spontaneously in the course of clinical care, not events that occur in the course of clinical trials or other studies.

Information on how to submit a voluntary report.
