# Purpose: Define procedure for FDA voluntary reporting of device related events.

**PRODCEDURE:**

An important part of the Food and Drug Administration (FDA) program for the regulation of medical devices is the surveillance of problems after entry of the device into the marketplace. Surveillance is performed to assure safety and timely identification of performance problems.

The 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. The 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).

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.

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.

Reporting Device Malfunctions:

In this facility:

1. Any employee that identifies a device malfunction, where there is a reasonable chance that the malfunction could recur and cause death or serious injury, will promptly notify the Laboratory Manager/General Supervisor and Laboratory Director or Medical Director.
2. The Director will review the incident and make a determination of the seriousness of the consequences.
3. **FDA Form 3500A** should be used for reporting events involving death or serious injury to a patient. The form can be found at the link provided https://www.fda.gov/safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting
4. The completed form will be submitted to the FDA and the manufacturer as soon as practicable, but not later than 10 days from the time the event was first identified.
5. All documentation and corrective actions taken along the process should be recorded and copies of records retained for a minimum of two years from the date of the incident.
6. If such an event gets reported additional actions must be taken the following year.

a. The Laboratory must submit an annual report of device-related events.

b. Annual reports must be filed on form 3419 by January 1 of each year.

|  |  |  |
| --- | --- | --- |
|  |  |  |