BATH COMMUNITY HOSPITAL
A Critical Access Hospital

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BATH COUNTY COMMUNITY HOSPITAL

POLICY AND PROCEDURES

DEPARTMENT: LABORATORY **EFFECTIVE DATE:** September 9, 2007
REVISED DATE:

POLICY: FDA Reporting of Device-Related Adverse Events

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.

POLICY:
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 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 (*http://www.fda.gov/opacom/morechoices/fdaforms/cdrh.html*) 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. See following page for blank copies of this form OR visit http://www.fda.gov/opacom/morechoices/fdaforms/cdrh.html.

The hospital 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 (http://www.fda.gov/opacom/morechoices/fdaforms/cdrh.html) or an electronic equivalent) by January 1 of each year. The laboratory or institution must keep records of MDR reports for 2 years.

PROCEDURE:
When a serious patient injury or death can be reasonable attributed to a medical device, notify the lab manager and complete form FDA 3500A as outlined in the instructions below. Blank forms can be found following this procedure and online at *http://www.fda.gov/opacom/morechoices/fdaforms/cdrh.html*

Instructions for completing FDA Form 3500A:

- All entries should be typed or printed in a font no smaller than 8 point.
- Complete all sections that apply. If information is unknown, not available or does not apply, the section should be left blank
- Dates should be entered as mm/dd/yyyy (e.g., *June 3, 2005 = 06/03/2005*). If exact dates are unknown, provide the best estimate.
- For narrative entries, if the fields do not provide adequate space, attach an additional page(s). The following **specific information** is to be incorporated:
  - Include the phrase *continued* at the end of each field of FDA Form 3500A that has additional information continued onto another page
  - Identify all attached pages as *Page __ of __*
  - Indicate the appropriate section and block number next to the narrative continuation
  - Display the User Facility, Distributor (Importer), or Manufacturer report number in the upper right corner as applicable
  - Include the firm's or facility's name in the upper right corner as well, if the report is from a user facility, distributor (importer), or manufacturer
- If the case report involves more than two (2) suspect medications attach another copy of Form FDA 3500A, with only section C or section D filled in as appropriate.
- If the event involves more than one suspect medical device, complete all applicable sections of **Form FDA 3500A** for the first device and a separate section D (Suspect Medical Device) and Blocks F9, F10, F13, and F14 for each additional device. Identify each report as *device 1*, *device 2*, etc.
- Manufacturers must complete and submit a separate **Form FDA 3500A** for each different suspect device. Each 3500A will be given a separate Manufacturer Report Number.
- If the suspect medical device is a single use device that has been reprocessed for use in humans, then the reprocessor is the manufacturer. The manufacturer can be either an Original Equipment Manufacturer (OEM), or a Reprocessor of Single-Use Devices, which also can be a User Facility that reprocesses Single-Use Devices. See the table on the following page.

Subject Device is:	Manufacturer is:
Single Use Device	Original Equipment Manufacturer (OEM)
Device designed to be reused	Original Equipment Manufacturer (OEM)
Single Use Device, reprocessed for reuse	Reprocessor
Single Use Device, reprocessed by Hospital or Health Care Facility	Hospital or Health Care Facility

- If no suspect medical device is involved in a reported adverse event (i.e., when reporting ONLY a suspect drug or biologic), ONLY sections A, B, C, E, and G are to be filled out:
  - Section G (*All manufacturers*) may be substituted for section D (*Suspect medical device*) on the front of the form to enable the submission of a one page form
  - If section G is reproduced on the front of the form it must be an identical reproduction of the original section G

- All submissions must be made in English, including foreign literature reports.
- Vaccines: Events involving vaccines should be reported to the Vaccine Adverse Event Reporting System (VAERS) on form VAERS-1(http://www.fda.gov/medwatch/safety/vaers1.pdf PDF format), available at http://vaers.hhs.gov or by calling 1-800-822-7967.
- Devices: Federal law provides that user facility reports that are required by law may not be used in private civil litigation actions unless the party who made the report had knowledge the report contained false information. 21 USC 360i(b)(3).

Complete instructions for form 3500A can be found at http://www.fda.gov/medwatch/report/instruc_10-25-05.htm.