FDA REPORTING PROCESS FOR DEVICE RELATED ADVERSE EVENT

SCOPE

The Laboratory will maintain a process for reporting of devise-related adverse events to the FDA and any other pertinent agencies as required by law. The process will be available to all employees to follow.

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 health care professionals to report the event

- If the event is death, the report must be made to the FDA and the devise manufacturer.
- If the event is serious patient injury, the report may be made to the manufacturer only.

The FDA defines a “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.

REPORTING PROCESS

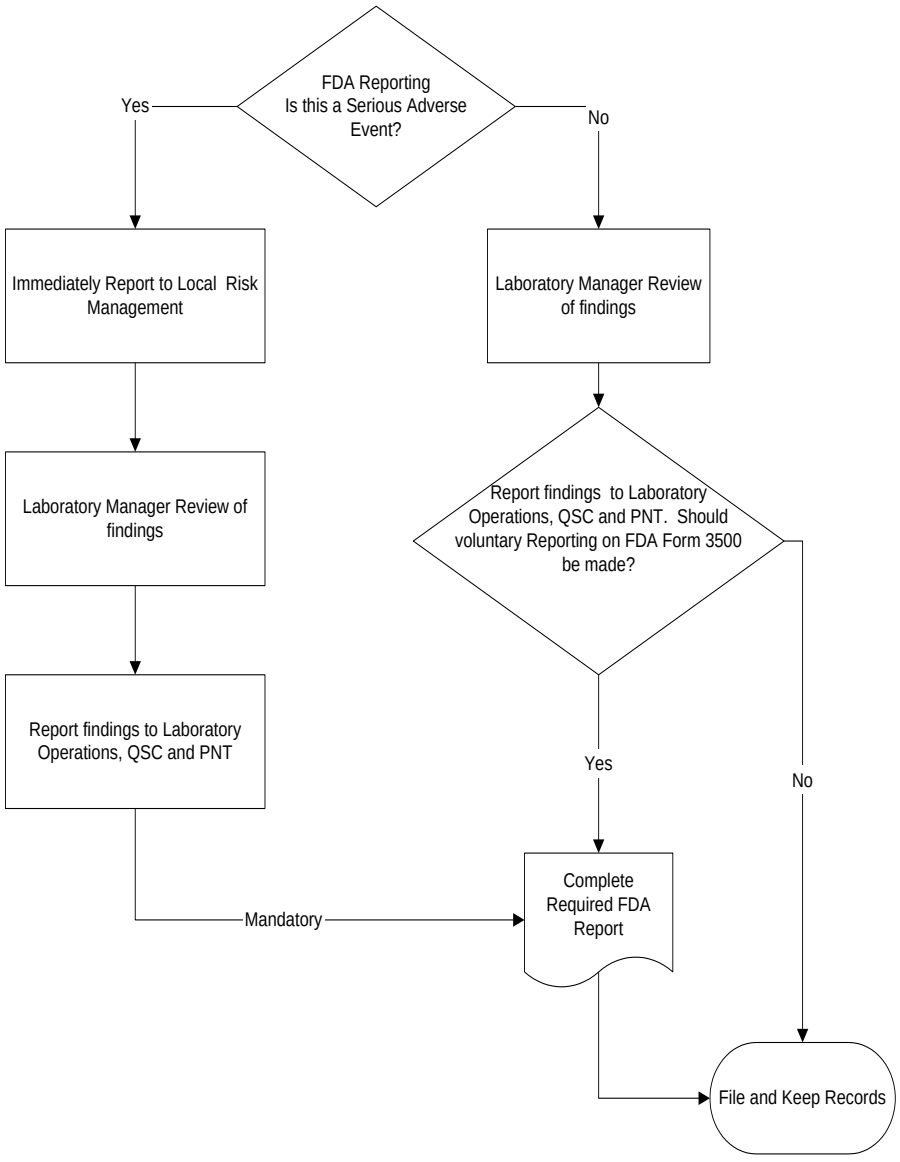
To determine if an event that occurs is a serious adverse event, incidents that occur within the laboratory must be reported to Laboratory management immediately. Laboratory management will determine in consultation with Risk management whether the event meets the criteria for mandatory reporting to the FDA.

If…	Then…
Incident meets criteria	Local Risk management will report to Regional Risk management and the FDA. (for in-patients the Department of health Services will also be notified to be in compliance with SB1301)
Incident does not meet criteria	Laboratory management will report to Laboratory operations Quality sub-committee and PNT committee to determine need for voluntary reporting. (see attached algorithm)

FDA REPORTING PROCESS FOR DEVICE RELATED ADVERSE EVENT, Continued

REPORTING PROCESS .

Laboratory FDA Reporting Process for Serious Adverse Event, Product Quality or Product Use Problem



updated 6/14/2007 fxu

FDA REPORTING PROCESS FOR DEVICE RELATED ADVERSE EVENT

Document History Page
Effective Date:

Change type: New, Major, Minor etc.	Changes Made to SOP - describe	Name of responsible person/date	Med. Director Authorized Reviewed/Date	Lab Manager Authorized Reviewed/Date	Date change Implemented
Minor	Regional Template revision	Ruby Co 6/6/18		Mary Lou Beaumont 7/31/18	8/1/18