WELLSTAR Health System

Department of Pathology and Laboratory Medicine

LABORATORY CONTINUING EDUCATION REPORT

Title:	FDA Voluntary Reporting of Device-Related Serious Adverse Patient Events

Signing /initialing below indicates that the employee has reviewed and understands the information presented/attached.

EMPLOYEE NUMBER	NAME	Signature/Initials

CAP CHECKLIST **GEN.20351** **Phase II**

The laboratory has a procedure for reporting device-related adverse patient events, as required by FDA.

When information reasonably suggests that any laboratory instrument, reagent or other device (including all instruments in the central laboratory, satellite laboratories, point-of-care testing programs, and accessory devices used for phlebotomy or specimen collection) has or may have caused or contributed to a patient death or serious patient injury, the FDA requires hospitals and outpatient diagnostic facilities, including independent laboratories, to report the event. If the event is death, the report must be made both to the FDA and the device manufacturer. If the event is serious patient injury, the report may be to the manufacturer only, unless the manufacturer is unknown, in which case the report must be submitted to the FDA. Reports must be submitted on the FDA Form 3500A (or an electronic equivalent) as soon as practical but no later than 10 days from the time medical personnel become aware of the event.

The 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. 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).
An adverse patient event that may have resulted from inherent limitations in an analytic system (e.g. limitations of sensitivity, specificity, accuracy, and precision) is not reportable.

The laboratory should have written procedures for
1) the identification and evaluation of adverse patient events,
2) the timely submission of MDR (medical device reporting) reports, and
3) compliance with record keeping requirements. A written record of participation in the overall institutional MDR process is required of laboratories that are part of a larger organization (e.g. hospital laboratories).

The laboratory should educate its personnel in the FDA MDR requirements.
The laboratory (or parent institution, as appropriate) 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 (for hospital-based laboratories only, or an electronic equivalent) or Form 3500 (for non-hospital-based laboratories) by January 1 of each year. The laboratory or institution must keep records of MDR reports for 2 years.

Additional information is available on the FDA website, at
http:/www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm

**In this context, "labeling" refers to all user instructions provided by the manufacturer.*

Evidence of Compliance:
✓ Records of MDR reports for reportable events, if applicable

(See WellStar policies below for guidance on how to handle a device-related adverse patient event. WHS LABORATORIES WORK WITH RISK MANAGEMENT AND BIOMEDICAL ENGINEERING TO DETERMINE COMPLEXITY OF EVENT, TO RESPOND TO EVENT, AND TO TAKE ACTION TO AVOID RECURRENCE.)

Note that a "medical device" is any item used to diagnose, treat, or prevent disease or injury that is not a drug, biologic, or food. This may range from items as simple as tongue depressors and needles or more complex devices such as ventilators.

INFORMATION FROM FDA

The Medical Device Reporting (MDR) regulation (21 CFR 803) contains mandatory requirements for manufacturers, importers, and device user facilities to report certain device-related adverse events and product problems to the FDA. The regulation specified that reports be filed on FDA Medwatch Form 3500A or an electronic equivalent.

Device User Facility Reporting Requirements
A "device user facility" is a hospital, ambulatory surgical facility, nursing home, outpatient diagnostic facility, or outpatient treatment facility, which is not a physician's office. User facilities must report a suspected medical device-related death to both the FDA and the manufacturer. User facilities must report a medical device-related serious injury to the manufacturer, or to the FDA if the medical device manufacturer is unknown.
User facilities must also submit annual reports to the FDA by January 1 of each year as described in 803.33.
Form 3419 Annual User Facility Report

Medical Device Reporting Annual User Facility Report - Form FDA3419
Instructions for Completing the Medical Device Reporting Annual User Facility Report, Form FDA3419

Please note that 803.30 (which addresses User Facility Reporting Requirements) does NOT state that device user facilities are required to report device malfunctions where the malfunction would likely cause or contribute to death or serious injury if the malfunction were to recur.
Although a user facility is not required to report a device malfunction, they can voluntarily inform the FDA of such product problems through MedWatch, the FDA's Safety Information and Adverse Event Reporting Program.
Healthcare professionals within a user facility should familiarize themselves with their institution's procedures for reporting adverse events to the FDA.
The FDA's "Medical Device Reporting for User Facilities" guidance document provides additional information.

WellStar Biomedical Engineering and Facility Safety Departments are familiar with the FDA online reporting process. Laboratory staff should be aware of the following policies to follow in the event of a device malfunction. Note that Biomedical Engineering will be involved if the device is electrically powered only.

WellStar Biomedical Engineering Policy and Procedure WBE009
SAFE MEDICAL DEVICE ACT INCIDENT REPORTING AND INVESTIGATION

PURPOSE:

To establish a protocol for monitoring and reporting incidents in which a medical device is connected to death, serious injury, or serious illness of any individual as required by the Safe Medical Device Act of 1990.

DEFINITIONS: SMDA - Safe Medical Device Act of 1990

POLICY:

The program is used to identify and document equipment problems, failures and/or user errors of patient care equipment that has had or could have had an adverse effect on patient safety and/or the quality of care.

Appropriate corrective action will be taken to protect the safety of all patients, visitors, and staff of WellStar Health System whenever information on a product related hazard or potential hazard is brought to the attention of WellStar Medical Imaging Service or WellStar Biomedical Engineering.

PROCEDURE:

The department manager shall report the occurrence involving possible patient, visitor, or staff injury to the WellStar Safety Officer and the Executive Director of Diagnostic Outreach or the Executive Director of Biomedical Engineering. Departments having medical equipment maintained by a source other than WellStar Medical Imaging Service or WellStar Biomedical Engineering shall be responsible for notifying both the facility's Safety Officer and WellStar Medical Imaging Service or WellStar Biomedical Engineering of any medical equipment problems that could have had an adverse effect on patient safety or the quality of patient care.

Immediately following notifications, the operator will get the following information:

. Patient name and ID number if patient is involved/injured
. Employee name and number if employee is involved/injured
. Exact time and date of malfunction
. Operator(s) name and employee number if different from (2) above
. Device/product name, model number, serial number, lot number and if applicable, the expiration date

If equipment could have been responsible for the death or injury of a patient or employee, it shall be reported immediately as previously stated and be placed in a secured area to await examination by the facilities Safety Officer. The equipment's operator(s) involved shall immediately:

. Before turning the power off and disconnecting the power, record all settings. Leave all switches, knobs, and controls in exact positions and all hoses, leads, and probes are to remain connected.
. Disconnect electrical power supply (if applicable) by unplugging unit and leaving the power switch in the "ON" or "OFF" position. (The position of the switch when the malfunction occurred). Discontinue use.

- Notify the department head, supervisor, or designee having responsibility over the device/product and the operator(s) of the equipment.
- If a patient is involved or injured complete an Incident Report describing in detail the failure or malfunction. Forward the report per facility guidelines. If a staff member has been injured, complete an Incident Report and forward to the Workers' Compensation Officer's office immediately unless medical treatment is provided to the staff member. In this instance, the office or facility providing the care will forward the incident reports to the Risk Management Department.

The facility Safety Officer shall document all details associated with a patient related incident and report all medical quipment patient related incidents to the facility's Safety Committee, the equipment manufacturer, or the FDA. The acility Safety Officer shall track the number of patient care incident reports that are suspected as device related.

The facility Safety Officer shall track the number of device related incidents that involve death, serious injury, or illness. The facility Safety Officer shall track the number of reports of suspected device related incidents that conclude a device layed a role in an incident versus the number of investigations that conclude no device played a role. This information hall be used to determine the effectiveness of the device-related incident reporting mechanism.

For medical equipment, Medical Imaging Service or Biomedical Engineering will offer to the facility Safety Officer the ervice of examining the equipment for any existing operational or electrical safety faults. Medical Imaging Service or Biomedical Engineering would then provide a written report of the inspection. Upon completion of the service intervention he owner department Manager and the facility Safety Officer shall receive a service report on the equipment. The ompleted work order will describe the corrective action taken parts used (if applicable) and part prices. . Should the ervice intervention be deemed as abuse or operator related, WellStar Medical Imaging Service, Wellstar Biomedical Engineeering or the equipment manufacture will provide in-servicing to the owner department. Service interventions with atient/operator related injuries will be documented as per policy with a copy of the service report forwarded by the accoun nanager to the department Manager and Facility Safety Officer.

A Medical Imaging Service or Biomedical Engineering Manager will assist the Safety Officer in meeting reporting esponsibilities under any federal or state regulations.

The WellStar Safety Officer will determine whether the device should be sequestered for a formal investigation or whether he incident only requires the equipment to be inspected/repaired and returned to service. Only the WellStar Safety Officer as the authority to return an impounded device to service. Only qualified personnel as directed by the WellStar Safety Officer may open, test, or operate an impounded device. A work order will be opened documenting the condition of the quipment and accessories. All settings of the equipment will be recorded. All documentation will be completed by the Medical Imaging Service or Biomedical Engineering technician and reviewed by the WellStar Safety Officer before the locuments are finalized.

The WellStar Safety Officer will determine the need for a third party to examine the equipment and/or to meet with the ersonnel involved. The WellStar Safety Officer will make this determination based on the nature of the Incident and/or njury, the degree of difficulty encountered in isolating and remedying the exact cause of the incident, and other factors pecific to the situation.

The facility's manager is responsible for ensuring any additional documentation is completed and for ensuring the Risk Manager and other personnel are notified as appropriate.

WELLSTAR

MEDICAL DEVICE FAILURE / USER ERROR			
Policy/ Procedure #	EC-15-01	**Effective Date**	July 2018
Category	Hospital	**Last Review/Revision**	December 2013
Sub-Category	Environment of Care	**Standards Leader**	Executive Director of Biomedical Engineering

POLICY STATEMENT:
The use of medical devices is often integral to the diagnosis and treatment of the patient. Medical devices may be manufacture with defects and recalled; may fail to perform during use of fail following implantation; or medical care professionals may encounter errors in the use of them. All such instance will be address appropriately to ensure patient safety remains the first priority.

PURPOSE: To define the process for responding to medical device incidents that have caused patient harm or death; medical device failures or user errors.

DEFINITION(S): None

EXCEPTIONS: None

CARE SETTING VARIATION:

❑ AMC ❑ AMC-S ❑ CH ❑ DH ❑ KRMC ❑ NFH
❑ PH ❑ SRH ❑ SGH ❑ WGHS ❑ WHH ❑ HC
❑ HOSPICE ❑ WMG

PROCEDURE:

	Required Action Steps	Performed By	Supplemental Guidance
IF ELECTRICALLY POWERED DEVICE EVENT OCCURS WHILE IN USE ON A PATIENT			
STEP ONE	1.1 Unplug or disconnect power supply	Patient Care Staff, Safety Officer, Risk Manager	
	1.2 Leave switches, knobs, dials, etc. in current position(s)	Patient Care Staff, Safety Officer, Risk Manager	
	1.3 If patient harmed, complete Incident Report	Patient Care Staff, Safety Officer, Risk Manager	Record: ♦ Patient information ♦ Employee name and number using the device ♦ Exact date and time of event ♦ Device name, model #, serial #, lot #, expiration date, etc.
	1.4 If staff harmed, complete Incident Report	Patient Care Staff, Safety Officer, Risk Manager	Record: ♦ Patient information ♦ Employee name and number using the device ♦ Exact date and time of event Device name, model #, serial #, lot #, expiration date, etc.

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	Required Action Steps	Performed By	Supplemental Guidance
STEP ONE CONT.	1.5 Contact Biomedical Engineering Department	Patient Care Staff, Safety Officer, Risk Manager	
	1.6 Report event to FDA according to requirements of SMDA	Risk Manager	
	1.7 Maintain all documentation of investigation	Risk Manager	
IF NON-POWERED DEVICE EVENT OCCURS WHILE IN USE ON A PATIENT			
STEP TWO	2.1 Retrieve as much of device as possible if retained as foreign body. Collect identifying device wrappers containing lot numbers, serial numbers, etc.		
	2.2 If patient harmed, complete Incident Report	Patient Care Staff, Safety Officer, Risk Manager	Record: ♦ Patient information ♦ Employee name and number using the device ♦ Exact date and time of event Device name, model #, serial #, lot #, expiration date, etc.
	2.3 If staff harmed, complete Incident Report	Patient Care Staff, Safety Officer, Risk Manager	Record: ♦ Patient information ♦ Employee name and number using the device ♦ Exact date and time of event Device name, model #, serial #, lot #, expiration date, etc.
	2.4 Report event to FDA according to requirements of SMDA	Risk Manager	
	2.5 Maintain all documentation of investigation	Risk Manager	

RELATED DOCUMENTS		
Policy / Procedure	EC-15 Medical Device Failure/User Error	
Job Aids		
Related Medical Record Form(s)		**Form/Item #**
Regulatory Requirements	EC.02.04.01 Food and Drug Administration (FDA) Safe Medical Device Act (SMDA)	
Evidence Based Practice References		
This replaces all previous SPP EC-15 and all previous SPP EC-15 shall automatically terminate upon the effective date set forth above.		

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