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Area	Laboratory-Quality
Applicability	All Beaumont Hospitals

Reporting Laboratory Device-Related Adverse Patient Events

Document Type: Procedure

I. PURPOSE AND OBJECTIVE:

A. The purpose of this document is to provide laboratory staff with a standardized process for the items listed below. It is imperative that laboratory managers/supervisors take active participation in educating laboratory personnel to Food and Drug Administration (FDA) medical device reports (MDR) requirements.

1. The identification and evaluation of adverse patient events
2. Proper participation in the hospital process of timely submission of medical device reports (MDR)
3. Compliance with record keeping requirements
4. Compliance with reporting as defined by the Safe Medical Devices Act (SMDA)

B. Objective:

1. The Safe Medical Devices Act (SMDA) requires that facilities report device-related deaths and serious injuries to the Food and Drug Administration (FDA) and/or the manufacturer.
2. As defined by the College of American Pathologists (CAP) Lab. GEN Checklist item GEN.20351 , *"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 manufacturer only, unless the manufacturer is unknown, in which case the report must be submitted to the FDA.

3. *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)."*
4. The Safe Medical Devices Act requires hospitals and other providers to report significant medical device adverse events to the FDA.
5. The **Clinical Engineering Department** is responsible to file these reports. It is the responsibility of laboratory staff to provide the Clinical Engineering Dept. with the necessary information/ documentation related to each "device-related" incident.

II. DEFINITIONS:

A. **Medical Equipment (Device):** An instrument, apparatus, machine or implant intended for use in the diagnosis, treatment or prevention of disease. (Medical Equipment Management Program: Overall Program Description)

B. **Serious Illness/Injury:** 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". (Medical Device Reporting for User Facilities, Dept. of Health and Human Services (HHS))

C. **Reportable Event Report Summary (ERS) / Incident:** Any process/incident inconsistent with the routine operation of the hospital or the routing care of patients in any setting. This includes errors that result in actual or potential injury to a patient or visitor, including near misses or unsafe conditions. RL Solutions Quality/Safety Report Instructions

D. **Investigation:** The appropriate Laboratory Manager and Technical/Medical Director, and Operations Specialist will investigate and evaluate the incident.

E. **Reporting:** All incidents that reasonably suggest that a medical device caused or contributed to the death or serious illness/injury of a patient will be reported. **The Clinical Engineering Department is responsible to file these reports**. Medical device variances are reviewed by Clinical Engineering and Medical Administration to determine if the medical device may have caused or contributed to the death, serious injury or serious illness of a patient or other individual.

1. If the device caused a **patient's death**, a report will be filed with the FDA.
2. If the incident resulted in a **serious illness or injury**, but not death, a report will be filed with the manufacturer. In the event of a serious illness or injury where the manufacturer in not known, a report will be filed with the FDA.
3. The report must be filed with the FDA **within 10 working days** after the hospital becomes aware of the reportable incident. *("Work-day" means Monday through Friday, excluding Federal holidays.)* (Medical Equipment Management Plan)

III. PROCEDURE:

A. **The person to first discover the variance incident should:**

1. Remove the instrument/reagent/other device from service – isolate if possible.
2. Boldly tag as "Out-of-Service – Do NOT use"
3. Complete a Service Request form (orange in color #1207) (Attachment to Medical Equipment Management Program: Repairs); include the Event Report Summary (ERS) report number on the form upon completion of submitting the ERS. Attach form to equipment/device.
4. Immediately complete an online ERS report including the section entitled, Equipment/Medical Device. Notify the section manager, technical and medical section directors, and Operations Specialist. The manager or section technical/ medical director is responsible to notify the department medical and administrative directors. The device will not be used until clearance is received by Biomedical / Clinical Engineering. Safety Event Reporting - RL Solutions; RL Solutions Quality/ Safety Report Instructions
   Include the following information on the ERS form:
   a. Full patient name
   b. Patient's Medical Record # (MRN)
   c. Incident date and time. Clearly define time
   d. Sex of patient
   e. Patient status (Inpatient/Outpatient, etc.)
   f. Equipment Involved/Malfunctioned? YES or NO. If the device is sent to Biomedical Engineering, include a photo-copy of the ERS form
   g. Injury Incurred?: Indicate the appropriate level of injury
   h. New Product/Device Involved?: Yes or No
   i. Severity: Indicate the appropriate level of injury
   j. Brief Factual Description: Give a *concise, complete and objective description of the incident*. Include the Corewell Health tag number and product description. Indicate whether the Patient and/or Family were notified. Indicate whether physician was notified.
   k. Notify the section supervisor that this ERS was written.

B. **The section manager/technical or medical director as soon as possible**, complete the FOLLOW-UP ACTIONS: When an error has contributed to an unanticipated outcome, the patient, and when appropriate, their family *"truthful and prompt disclosure to patients and families of adverse outcomes or unintended occurrences which impacted the patient's care and to provide caring and compassionate follow-up assistance when needed*". Refer to Disclosure of Safety Events for disclosure guidelines.

IV. REFERENCES:

A. Medical Device Reporting for User Facilities, Dept. of Health and Human Services, Public Health Service, Food and Drug Administration, Center for Devices and Radiological Health (DRH). Current version

B. RL Solutions Quality/Safety Report Instructions

C. Serious Safety Events

D. Equipment Management Program: General Safety Precautions

E. Medical Equipment Management Program: Repairs

F. Disclosure of Safety Events

G. College of American Pathologists, Laboratory General Checklist, Current version

H. Standards for Blood Banks and Transfusion Services, Current version

I. 21 CFR 803 – Medical Device Reporting

Approval Signatures

Step Description	Approver	Date
CLIA Site Licensed Medical Directors	Ann Marie Blenc: System Med Dir, Hematopath	8/27/2024
CLIA Site Licensed Medical Directors	Subhashree Mallika Krishnan: Staff Physician	8/26/2024
CLIA Site Licensed Medical Directors	Ryan Johnson: OUWB Clinical Faculty	8/15/2024
CLIA Site Licensed Medical Directors	Muhammad Arshad: Chief, Pathology	8/15/2024
CLIA Site Licensed Medical Directors	Kurt Bernacki: System Med Dir, Surgical Path	8/15/2024
CLIA Site Licensed Medical Directors	Jeremy Powers: Chief, Pathology	8/15/2024
CLIA Site Licensed Medical Directors	Masood Siddiqui: Staff Pathologist	8/14/2024
CLIA Site Licensed Medical Directors	Hassan Kanaan: OUWB Clinical Faculty	8/14/2024
CLIA Site Licensed Medical Directors	John Pui: Chief, Pathology	8/14/2024

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Operations Directors	Amy Knaus: Dir, Pathology Service Line	7/11/2024
Operations Directors	Elzbieta Wystepek: Dir, Lab Operations B	7/11/2024
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Applicability

Dearborn, Farmington Hills, Grosse Pointe, Royal Oak, Taylor, Trenton, Troy, Wayne