Title: **Device-Related Adverse Patient Events Reporting**

Department: Laboratory Medicine Administration

Subject: FDA reporting of adverse patient events

Policy Number: 100-027-03

Effective Date: August 22, 2005

Policy:
The UW Medicine Department of Laboratory Medicine is committed to ensuring the appropriate and timely reporting of adverse patient events. Food and Drug Administration (FDA) regulations require reporting to the FDA and/or the device manufacturer of adverse patient events when information reasonably suggests that any laboratory instrument, reagent or other device has caused or contributed to a death or a serious injury of any patient. The regulations include all instruments in the central laboratory, satellite laboratories, point-of-care testing programs and/or accessory devices used for phlebotomy or specimen collection.

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, regardless of the immediacy of the surgical or medical intervention.

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 user error 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, precision, etc) is not reportable and is not covered under this policy.

All staff will be made aware of this policy and informed of their obligations in this process through training.

Procedure:

The identification and evaluation of adverse patient events is primarily managed and reported through the parent facility (e.g. UWMC or HMC). A detailed procedure for this can be found in the risk management documents number 115-5 "Medical Device-Related Event

Reporting" at https://uwmc.uwmedicine.org/sites/PoliciesProcedures/apop/Pages/115-5.aspx
Report submission and record keeping is performed in Risk Management/ Clinical Engineering.

User facilities (such as hospitals and clinics) **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. A user facility is not required to report a device malfunction, but can voluntarily advise the FDA of such product problems using the voluntary MedWatch Form FDA 3500 under FDA's Safety Information and Adverse Event Reporting Program. Laboratory staff are to be informed of both mandatory reporting requirement and voluntary reporting options. Staff reporting will be consistent with the parent facility procedures, and usually involve lab superviror/managers and faculty, including compliance with HIPAA privacy concerns.

References:

General Information:

Department of Health and Human Services, "Medical Device Reporting for User Facilities", April 1996, http://www.fda.gov/cdrh/mdruf.pdf

Food and Drug Administration, "Medical Device Reporting (MDR) – General Information", 9/22/2002, http://www.fda.gov/cdrh/mdr/mdr-general.html
https://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm#howtoreport (accessed 8/9/2017)

UWMC specific policies:

Risk Management Policy 115-5 "Medical Device-Related Event Reporting", https://uwmc.uwmedicine.org/sites/PoliciesProcedures/apop/Pages/115-5.aspx

Risk Management Policy 115-3 "Defective Equipment and Supply Management", https://kow1.mcis.washington.edu/manuals/uwmc_apop/115/115_3.html

Equipment Management Policy 47-2 "Medical Equipment Management", https://uwmc.uwmedicine.org/sites/PoliciesProcedures/apop/Pages/47-2.aspx

HMC specific policies:

Risk Management Policy 115.3 "Non-Punitive Event Occurrence Reporting https://hmcweb.washington.edu/ADMIN/APOP/QualityAssuranceRiskMgmt/NON-PUNITIVE+EVENT+OCCURRENCE+REPORTING+115.13.htm

Clinical Engineering Policy 75.9 Biomedical – Defective Equipment Reporting

https://hmcweb.washington.edu/ADMIN/APOP/MaterialsManagement/BIOMEDICAL+–+DEFECTIVE+EQUIPMENT+REPORTING.htm

Medical Staff Policy 80.8 Adverse Sentinel Events, https://hmcweb.washington.edu/ADMIN/APOP/MedicalStaff/ADVERSE+SENTINEL+EVENTS.htm

Medical Staff 80.20 Disclosure of Unanticipated Outcomes, https://hmcweb.washington.edu/ADMIN/APOP/MedicalStaff/DISCLOSURE+OF+UNANTICIPATED+OUTCOMES.htm

Revision History:
Version 2 – 5/9/11 - Removed review date from posted version. Reauthorized by new director. Replaced Renee Lang with Phyllis Daum as process owner due to Renee's retirement.

Version 3 – 8/9/17 Added paragraph on MedWatch Mandatory and Voluntary FDA reporting. Added "primarily" regarding facility reporting. Updated UWMC policy name and links. Replaced Phyllis Daum with Wing Yan Tam as process owner due to Phyllis's retirement. Added link to current FDA website on MDR.

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Process Owner:	Wing Yan Tam, Lab Coordinator	Date: August 10, 2017
Authorized by:	Dr. Geoffrey Baird, Laboratory Medicine Chairman	Date: August 10, 2017