Wake Forest Baptist Medical Center	Reporting Quality Issues in the Laboratory	Dept:	Pathology
		Effective Date:	Sept 2005
		Revised Date:	Jan 11, 2019
		Contact:	Laboratory Compliance and QA
Name & Title: CLIA Lab Director		Date:	1/16/19
Signature:			

1) **General Procedure Statement:**

a. **Scope:** Defines the means for laboratory employees to report quality issues as related to test quality and laboratory safety, employee concerns and/or safety, patient safety, physician concerns and device related adverse patient events.

It is the policy of the Laboratories of the Department of Pathology to adhere to and comply with all regulatory standards as they pertain to the reporting of safety and quality related issues. Employees have the right to report concerns without the fear of retaliation and may do so by multiple avenues:

- Face to face with Lab Management,
- Via internal electronic reporting systems (RL6) (known or anonymous)
- Wake Forest Baptist Health Compliance Hotline (known or anonymous)
- Through any of our Accrediting Agencies such as the College of American Pathology, The Joint Commission, CMS/CLIA, American Association of Blood Bank, Food and Drug Administration, etc.
- Laboratory Compliance Officer

This procedure applies to all laboratory sections and is to be used in conjunction with the hospital RL Solutions (RL6) occurrence reporting system, the internal laboratory CAPA process, the laboratory quality reporting process and when appropriate Risk Management.

b. **Responsible Department/Party/Parties:**
   i. Procedure owner: Department of Pathology
   ii. Procedure: Department of Pathology
   iii. Supervision: Department of Pathology Laboratory Compliance, Quality and Safety, Laboratory Safety Officer

iv. Implementation: Department of Pathology Section Medical Directors, Associate Directors, Section Manager/Assistant Managers, Lab Faculty and Staff and CLIA Laboratory Director

2) **Definitions:**

a. **Sentinel Event:** defined by The Joint Commission (TJC) as any unanticipated **event** in a healthcare setting resulting in death or serious physical or psychological injury to a patient or patients, not related to the natural course of the patient's illness.

b. **Medical Device Related Events (MDR)** – Events that require remedial action to prevent an unreasonable risk of substanstantial harm to the public health and other types of events designated in writing by the FDA.

3) **Procedure:**

a. Any laboratory test quality or laboratory safety issue, physician concern or adverse patient event must be reported.

i. Events should first be reported to the Section Manager/Assistant Manager and proceed up the Laboratory Chain of Command as necessary.

ii. Depending on the type of event, it may also be necessary to proceed with reporting through RL6 or implementation of the Laboratory CAPA process or, for Device related issues, notify Risk Management. Some situations may require a combination of these reporting mechanisms. (Refer to individual procedures for RL6, CAPA and Device related issues to determine when each method should be used.)

b. Risk Management handles investigation and reporting of Sentinel Events and Medical Device Related (MDR) problems to the appropriate agencies. These problems should be reported as an RL6 after notifying Section Management.

Laboratory staff should also be aware that they too can report Adverse Patient Events that have occurred as the result of a device related incident directly to the FDA. Information and training on how to report such incidents can be found on the FDA website at the following location:

http:/www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm *

c. Physician concerns are referred by the Section Manager to either the Section Medical Director, CLIA Lab Director or the Department of Pathology Chairman and reported as part of the monthly Quality Report for each section.

d. Any laboratory test quality and safety concerns that an employee feels is not being satisfactorily resolved by the laboratory or the hospital organization may be referred directly to any of the following healthcare oversight organizations:

- CAP (College of American Pathologists) at 866-236-7212

- TJC (The Joint Commission)
  www.jointcommission.org/report_a_complaint.aspx
- Centers for Medicare and Medicaid Services (CMS) Central Office, Division of Laboratory Serives (CLIA), in Baltimore, Maryland at 1-877-267-2323 extension 63531
- FDA

  http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.ht

4) **Review/Revision/Implementation:**
   a. Review Cycle: 2 years
   b. Office of Record: Laboratory Compliance, Quality and Safety

5) **Related Policies:**
   Medical Center *No Retaliation Policy*
   Procedure for Completing CAPA
   Medical Center *Patient Safety and Quality Assessment Reporting Responsibilities*

6) **References, National Professional Organizations, etc.:** GEN.20325, GEN.20316, GEN.20208

7) **Attachments:** N/A

8) **Revision Dates: January 23, 2017**

Review Date	Revision Date	Signature