QUALITY POLICY: OCCURRENCE MANAGEMENT

7.0 PURPOSE

To describe the policy for data collection, analysis, and follow-up of issues identified as requiring process improvement through corrective and preventive action. This results in efficiency, satisfied customers and employees, and compliance with regulations and standards. The FHS Laboratory is focused on being aware of the occurrences that signal its malfunctioning processes so that problems can be corrected, quality ultimately improved, and risk lessened.

7.1 CLASSIFICATION OF INFORMATION

Terms such as incidents, errors, accidents, variances, nonconformances, deviations, and occurrences are often used interchangeably. The following definitions are used in the FHS Laboratory Occurrence Management process:

Occurrence: An event which adversely affects, or has the potential to adversely affect patients or services, represents non-compliance with statutory requirements and / or established Laboratory Services policies and procedures, or non-fulfillment of a specified requirement. Occurrences are categorized as one of the following:

- **Accident:** Unexpected or unforeseeable event or occurrence, generally beyond the control of the laboratory.

- **Complaint:** Any issue of concern or dissatisfaction raised by a customer.

- **Error:** An occurrence that represents a deviation from applicable standards or established specifications that is within the realm of control of the laboratory. A deviation may be planned and approved by management in advance of implementation, or occur because of error. Errors are classified as follows:
  1. Slip—an error in an automatic process.
  2. Mistake—an error caused by poor judgment or lack of knowledge.

7.2 DETECTION OF OCCURRENCES

The laboratory becomes aware of undesirable occurrences from a number of sources.

- **Customer Complaints:**
  Laboratory customers include physicians, nurses, patients, and hospital employees.

- **Employees:**

Employees frequently discover problems with processes and procedures inside and outside their work responsibilities that can often generate further problems.

- **Review of appropriate sources of information:**
  Review of assessment results, proficiency testing results, quality control records, result review reports, error correction reports, and exception reports.

7.3 DOCUMENTATION OF OCCURRENCES

See R-PR-AD-0901, Occurrence Management, and R-W-AD0902, Use of the Quality Improvement Monitor Tool.

- The individual who detects an occurrence records the details that will facilitate the investigation and resolution. The Quality Improvement Monitor Tool (QIM), R-F-AD0902, is designed and used for this purpose. After completion, each QIM is routed to the appropriate manager.

- Each occurrence is assessed by that manager for whether it affects the safety of the patient, and / or the quality of the product, or service, or potentially affects the safety or quality. If so, it is routed immediately to the Quality Manager, who routes to Risk Management.

- When any lab employee action results in a QIM or other quality incident report, the employee receives feedback on the occurrence (if more that a slip). Quality incident review and/or trending occurs in staff meetings and or staff counseling as appropriate.

- If the problem involves a fatality, documentation must be done immediately and reported to the appropriate regulatory offices. (See Reporting below)

- An ongoing log of reported occurrences is maintained by each manager. This log serves to track individual occurrences for analysis and Process Improvement.

7.4 REPORTING

- Quality issues are discussed monthly at the FHS Laboratory Management Committee Meeting.

- Any reports of adverse reactions due to transfusions that are confirmed to be fatal, are reported to the FDA by Phone within 24 hours and by writing within 7 days.

- If the occurrence affects the safety, purity, or potency of any blood product made available for distribution, an FDA Biological Deviation Report is submitted electronically to the FDA within 45 days.

- All Occurrences assessed as affecting patient safety or having the potential to affect patient safety are reported ASAP to Risk Management using hospital incident reporting processes, for follow up with other departments as deemed necessary.

- The FHS Laboratories follow the FHS Policy for reporting device-related adverse patient events as required by the FDA. See FHS Policy 510.00 Equipment Management.

- A dedicated CAP phone line for Quality and Safety concerns and an FHS patient safety hotline are posted for employee information.

7.5 MATRIX TO PROCESS IMPROVEMENT

Information about the types and causes of occurrences is essential to process improvement. Occurrence analysis provides information for process improvement on the following:

- Which errors occur most frequently
- Reasons for customer dissatisfaction
- Opportunities for improvement in processes to prevent recurrence
- Tracking and trending of laboratory quality issues is reported quarterly at Laboratory Management meetings.