Policy Statement	The Laboratory seeks to increase patient safety and minimize risk to the hospital through establishment of an occurrence reporting system. Expected outcomes of the system are identification of deviations from procedure, process improvement and opportunities to collaborate with external customers to continuously improve Laboratory services. The Laboratory is dedicated to ensuring that this process is accomplished in a cooperative atmosphere.
Purpose	The Laboratory maintains its Occurrence Reporting System to detect, investigate, report, track and trend events that do not conform with established policies, processes, and procedures. Occurrence report forms (ORFs) submitted by Laboratory associates are entered into a database, classified and analyzed with follow-up actions as required. Cumulative reports are monitored for developing trends; this information is used to guide Laboratory quality and process improvement activities.
Scope	This policy applies to all associates and physician affiliates in all sections of the Laboratory.
Responsibility	It is the responsibility of the Laboratory associate that encounters the non-conforming event to complete an ORF including any actions taken to resolve the issue or appropriately communicate information to a responsible associate for the completion of the ORF. It is the responsibility of the supervisory individual to complete the ORF Follow-Up Form and ensure that the issue is resolved to the extent possible and if necessary, develop an action plan for resolution and/or prevention of a similar event. It is the responsibility of the Quality Coordinator or designee to review and disperse the ORFs and ORF Follow Up form to the appropriate supervisory individual, as needed.
Types of Events	Significant, unexpected or unusual events are to be documented using the occurrence reporting system. These non-conforming events include, but are **not** be limited to: ➢ Patient, visitor or associate safety issues or injuries ➢ Failure to provide appropriate customer service ➢ Unsafe working conditions ➢ Equipment failures and maintenance issues ➢ Unplanned computer downtime ➢ Significant quality control problems or inappropriate remedial actions or documentation

	➢ Inventory shortages and wastage ➢ Unusual events or requests ➢ Deviations from policy or procedure ➢ Service issues such as delay of test results ➢ Communication issues ➢ Vendor Recalls ➢ Incomplete requisitions or request forms ➢ Order entry errors ➢ Rejected or returned specimens ➢ General complaints
Process	The Occurrence Reporting System includes the following activities: 1. Documenting the specific event and any actions taken to resolve the issue on discovery. 2. Completion of LADM 8000 Ff ORF Follow-Up Form for internal events. 3. Classification of the occurrence and entry into the system database. 4. When appropriate, formation of a team to investigate events that have the potential to affect the quality and safety of Laboratory Services and personnel. Resources outside the Laboratory may be utilized to achieve resolution (i.e. Employee Health, Risk Management, Human Resources, Facilities Management, etc.). 5. Implementation of corrective actions to eliminate the root cause and prevent recurrence, as necessary. 6. Monitoring corrective actions for effectiveness. 7. Continuous updating of the system database to allow for trending of events. 8. Reporting of analysis as appropriate.
Occurrence Review	Reported occurrences are reviewed for completeness of information and to determine if there is a need for additional actions to resolve the issue.

	1. All ORFs are sent to the immediate supervisor of the laboratory section(s) impacted by the occurrence if internal to the lab, and the Lab Quality mailbox for review using the email system. 2. LADM 8000 Ff is completed to document follow of the occurrence for internal events. 3. The ORF is assigned an Occurrence Report Form Number and entered into the database. 4. Critical issues regarding patient or associate safety must be addressed immediately. Prompt notification of a Pathologist and the Administrative Director is required if the issue is deemed critical and will be forwarded to the Executive daily huddle. 5. Complex issues will be addressed using-Root Cause Analysis (RCA) and/or other related quality tools. 6. The ORF and additional documentation (i.e. requisition, etc.) are filed electronically in the Occurrence Reporting System database. 7. Documentation of RCA is kept on file. After completion the contents of the file will be scanned into a folder and saved electronically.
Reports	Reports associated with Occurrence Management are reviewed by Laboratory leadership at the Laboratory Management Council meeting as needed. Supervisory personnel can request ad-hoc reports as needed. Reports generated from the Occurrence Reporting System database allow: 1. Quantification of occurrences by type and location. 2. Trending of events over time to aid in prioritizing process improvement opportunities including identifying needs in associate training and education. 3. Reports of identified trends, corrective actions, quality projects and process improvements to the appropriate

	oversight, i.e. Quality, PI and/or MSQA committees, etc. Quality, PI and MSQA committees report to the Patient Safety Committee.
Management	The Quality Coordinator reviews each reported occurrence to detect significant or sentinel events requiring root cause analysis and referral to Risk Management. The reports for less egregious events are reviewed for completeness and then forwarded to the appropriate internal/external supervisory personnel. Process Improvement: The collected data is compiled and analyzed for trends or patterns, additional consideration may be given to events where the patient would have been harmed had the event not been caught (near-miss). Assessment of Incident Reports, failure to reach benchmark, audits and other events not captured in the database may also be assessed. The information is presented at a Laboratory Management Council to determine criticality. Considerations include: • Recurring events that compromise patient safety • Continued nonconformance that could compromise the Laboratory or hospital's license or accreditation • Issues that represent a significant source of customer dissatisfaction • Issues that represent an unwarranted financial impact to the laboratory and/or hospital A consensus approach by the group will determine which trends or nonconforming event(s) will be proposed for assessment. The Medical Director and Laboratory Administrative Director will review the selections and approve or reject the proposal. At the direction of the Medical Director, selected process improvement projects are reported to the appropriate oversight (i.e. Quality & PI and/or MSQA Committees, etc.). Quality, PI and MSQA Committees report to the Patient Safety Committee. System Effectiveness: Laboratory leadership team will review the Occurrence Reporting System for effectiveness annually. The results of the review are included as part of the assessment of the Laboratory Quality Plan. Elements reported may include: a. Team assessments resulting from non conforming events and/or ORF trending

	b. Future opportunities for improvement c. Unresolved issues that concern patient safety d. Significant waste reduction The annual report for the effectiveness of the ORF system is included in the Quality Plan Assessment.
Related Documents	LADM 0000 QP Lab Quality Management LADM 8000 R Laboratory Occurrence Reporting Procedure LADM 8000 Ja Laboratory Occurrence Reporting System LADM 8000 Fa Laboratory Occurrence Reporting System-General ORF Form LADM 8000 Fb Laboratory Occurrence Reporting System-Outreach ORF Form LADM 8000 Fc Laboratory Occurrence Reporting System-Transfusion Services ORF Form LADM 8000 Fd Laboratory Occurrence Reporting System-Corelab ORF Form LADM 8000 Fe Laboratory Occurrence Reporting System-Support Services ORF Form LADM 8000 Fh Transfusion Service Rejected Specimens LADM 8000 Ff ORF Follow Up Form LADM 8000 Fg Laboratory Occurrence Reporting System-Referral Testing ORF Form LADM 8000 Fh Transfusion Service Rejected Specimens
References	Application of a Quality Management System Model for Laboratory Services-Approved Guideline- 3rd Edition, GP26-A3, Clinical Laboratory Standards Institute. Management of Nonconforming Laboratory Events – GP32 –A Clinical Laboratory Standards Institute Laboratory General Checklist, College of American Pathologists, current version. LADM 0000 QP, Laboratory Quality Plan.