Franciscan Health System

QUALITY POLICY 1 ORGANIZATION

☑ St. Joseph Medical Center Tacoma, WA
☑ St. Francis Hospital Federal Way, WA

⊠ St. Clare Hospital Lakewood, WA ⊠ St. Anthony Hospital Gig Harbor, WA ⊠ St. Elizabeth Hospital Enumclaw, WA □ PSC

PURPOSE

To describe the FHS Laboratory quality policy as it relates to the organizational structure and management responsibilities.

Quality Responsibilities

| Staff Position | Quality Responsibility |
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| 1. Medical Director of Laboratory | Oversees quality of medical aspects of Clinical and Anatomic Pathology as well as operations of Anatomic Pathology. Responsibility and authority for all medical and technical policies, processes, and procedures, including those that pertain to laboratory personnel and test performance, and for the consultative and support services that relate to the care and safety of transfusion recipients. |
| 2. Laboratory Director-Associate Vice President | Responsible for the overall quality of operations of Franciscan Health System Laboratories, and is designated as the Laboratory's Responsible Head. Responsible for implementing organizational priorities in the laboratory. |
| 3. Laboratory Managers | Monitors daily quality of FHS laboratories in their area of responsibility. Reviews logs, and tracks and trends quality monitors, directing for corrective action or root cause analysis if indicated. Review proficiency test results, Result Review Reports and Exception Reports for quality issues. Log QIMs for their areas, routing issues to the Lab Quality Committee or to FHS Risk Department as appropriate. Serves as a member of the Laboratory Quality Committee. |
| 4. Regulatory Compliance Manager | Responsible for daily quality in areas of safety, regulatory, point of care, staff education, and compliance. Reviews, logs, tracks and trends Employee Incidents, reporting to appropriate entities. Reports to appropriate agencies as required. Oversees the Quality Plan and Quality System. Logs and routes QIMs to FHS Risk Department as appropriate. Serves as a member of the Laboratory Quality Committee. |
| 6. Microbiology/Urinalysis Manager | Review proficiency testing results, daily Result Review Reports and Exception Reports for quality issues. Reports to appropriate committees and agencies as required. Log QIMs for their areas, routing to the Laboratory Quality Committee or Regulatory Manager as appropriate. |
| 7. Science & Technology Manager | Review daily Result Review and QC Outlier Reports, proficiency results and implements corrective action if indicated. Monitors RALS and Medical devices connectivity, and general lab instruments. Addresses issues as required. Work with LIS staff to resolve any LIS-related issues. Log QIMs for their areas, routing to the Laboratory Quality Committee or Regulatory Manager as appropriate. |
| 8. Transfusion Service Manager and TS Medical Director | Has responsibility and authority for Transfusion Service operations, and compliance with BB/TS Standards and applicable laws and regulations. Reviews proficiency test results, daily Result Review, Correction, and Exception Reports. Logs QIMs for the Transfusion Service routing to the Laboratory Quality Committee or Regulatory Manager as appropriate. |
| 8. Employees | Trained and encouraged to take responsibility for quality and safety in their area of work and use the tools designated for quality improvement opportunities, such as Quality Improvement Monitor (QIM), Employee Incident Reporting System (IRIS), and Client Relationship Management (CRM). |

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INTERDISCIPLINARY QUALITY ACTIVITY

FHS Laboratory Managers participate in interdisciplinary performance improvement teams throughout the hospital. These activities provide feedback for quality monitors and are discussed at the Laboratory Management meeting which serves as the Laboratory Quality Committee. Committee members are:

- Medical Director or designee
- Associate Vice President
- Operations Managers from all FHS Lab sites
- Science and Technology Manager
- Transfusion Service Manager
- Transfusion Service Medical Director
- Regulatory Compliance Manager
- Microbiology and Urinalysis Manager

Significant quality issues may be presented at the Franciscan Laboratory Operation and Technical (FLOAT) management meeting to prevent similar occurrences in another laboratory. Quality activities and outcomes are summarized and presented at this meeting annually. Quality indicators for the department are determined and monitored as a regional laboratory. Quality issues are discussed and presented at technical and operational staff meetings.

DOCUMENT APPROVAL Purpose of Document / Reason for Change:

Updated for current titles; referenced Lab Management Team as the Laboratory Quality Committee. Standardized some responsibilities such as proficiency testing review, RRR, and error reports, etc.

No significant change to process in above revision. Per CAP, this revision does not require further Medical Director approval.

| Committee Approval Date | | Medical Director Approval (Electronic Signature) | Axide D. Burde | bondl, MS 8/30/13 |
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