QUALITY PLAN INTRODUCTION

☒ St. Joseph Medical Center Tacoma, WA ☒ St. Clare Hospital Lakewood, WA ☒ St. Elizabeth Hospital Enumclaw, WA
☒ St. Francis Hospital Federal Way, WA ☒ St. Anthony Hospital Gig Harbor, WA ☒ PSC

SCOPE OF APPLICATION

This Quality Plan describes and details the Quality System which applies to the operations of the laboratories of Franciscan Health Systems, to include the laboratories of St. Joseph Medical Center of Tacoma (SJMC), St. Anthony Hospital of Gig Harbor (SAH), St. Clare Hospital of Lakewood (SCH), St. Francis Hospital of Federal Way (SFH), and St. Elizabeth Hospital (SEH) of Enumclaw, WA This Quality Plan is an evolving document that will be reviewed annually as a result of self-assessment activities, organizational changes, and technical developments.

OBJECTIVES

Franciscan Health Systems Laboratory Quality Plan is organized to monitor functions and systems in the Laboratory through the performance of self-assessment audits, error management, and customer feedback. Quality of processes, products, and people are the cornerstones of the Franciscan Healthcare System. We are guided by law, conforming to the regulatory standards required by local, state, and federal government agencies.

We adhere to high standards for quality by conforming to requirements for accreditation established by the following:

- College of American Pathologists
- The Joint Commission (TJC)
- AABB
- CLIA
- DOH

REGULATORY UPDATES

Multiple mechanisms are used to assure that the laboratory remains up to date on changes to, or new state, local, or federal regulatory requirements such as:

- FHS Chief Safety and Regulatory Officer
- AABB, CAP, CMS, CLMA, Washington State Department of Health/Lab Quality Assurance, Joint Commission websites, electronic updates, and mailings
- Organizational email routings such as those from H2E, AACC, ASCP, FDA, etc.

TERMS OF CAP ACCREDITATION

Adherence to the Terms of Use is required for the CAP Certification Mark of Accreditation. The College of American Pathologists (CAP) requires immediate notification should any of the following conditions occur:

- Investigation of the laboratory by a government entity or other oversight agency, or adverse media attention related to laboratory performance; notification must occur no later than 2 working days after the lab learns of an investigation or adverse media attention. This notification must include any complaint investigations conducted or warning letters issued by any oversight agency (i.e. CMS, State Department of Health, The Joint Commission, FDA, or OSHA); notification must occur no later than 2 working days after the lab learns of an investigation or adverse media attention.

- A lab must cooperate with CAP when the lab is subject to a CAP investigation or inspection
- A lab must notify the CAP as soon as it finds itself to be the subject of a validation inspection
- Discovery of actions by laboratory personnel that violate national, state, or local regulations
- Change in laboratory test menu (notification must occur prior to starting new patient testing)
- Change in location, ownership or directorship of the laboratory

DESCRIPTION OF QUALITY PLAN

A documented Quality System is required by the ISO 9000 series quality standards, the AABB and the CLSI Quality System Model for Healthcare. This Quality Plan states the policy of the Franciscan Health System (FHS) Laboratories, and describes the Quality System implementation in writing. The Quality System is documented in the following:

- Level I Documents: Quality System Policies
- Level II Documents: Quality and Operating System Processes
- Level III Documents: Procedures, Work Instructions
- Level IV Documents: Forms and Records

QUALITY SYSTEM POLICIES

All laboratory staff receive training at the time of hire on the FHS Quality Plan. The Quality System Policy Essentials are:

1. Organization
2. Personnel
3. Equipment
4. Purchasing/Inventory
5. Process Control
6. Documents and Records
7. Occurrence Management
8. Assessments: Internal and External
9. Process Improvement Through Corrective Action
10. Facilities and Safety
11. Information Management
12. Customer Service

Quality Systems Policy Essentials are the cross-functional quality elements that are uniformly applied to each of the following operating systems of the FHS Laboratories:

- Patient Assessment
- Test Requests
- Specimen Collection
- Specimen Transport
- Specimen Receipt/process
- Testing and Review
- Lab Interpretation
- Results Reporting
- Post-Test Specimen Management
- Information System
- Clinical Interpretation/Consultation
- Customer Service

DOCUMENT APPROVAL **Purpose of Document / Reason for Change:**			
Added new terms of accreditation to Introduction; added training for QP occurs at new hire for staff • Notification must occur no later than 2 working days after the lab learns of an investigation or adverse media attention. • A lab must notify the CAP as soon as it finds itself to be the subject of a validation inspection • Discovery of actions by laboratory personnel that violate national, state, or local regulations • Adherence to Terms of Use is required for Cap Certification Mark of accreditation • A lab must cooperate with CAP when the lab is subject to a CAP investigation or inspection			
☐ *No significant change to process in above revision. Per CAP, this revision does not require further Medical Director approval.*			
Committee Approval Date	☒ Date: 8/29/13 ☐ N/A – revision of department-specific document which is used at only one facility	**Medical Director Approval** *(Electronic Signature)*	Linda D. Blumenthal, MD 8/23/13