

Sutter Health Valley Area Clinical Laboratory Services	TRAINING DOCUMENT
Initiation Date: 5/20/10 Revision Date: 10/16/13, 8/30/17, 9/28/21 Written by: Nancy Anderson, CLS Christine Flaherty, CLS Revised by: H.Rabinovitz, E.Padilla	Quality Management Program

Overview The employees of the Sutter Health Clinical Laboratory Services require knowledge of essential quality and compliance processes and policies. This document describes key quality essentials in pre-analytic, analytic and post-analytic processes for both acute care and ambulatory laboratory services.

- Policy**
- The Laboratory maintains an over-arching Quality Policy - referred to as “*Our Commitment*” - that states our intent for providing a high quality service that is customer-focused.
 - Decisions, agreements and behaviors of Laboratory management and staff are aligned and consistent with the Quality Policy.
 - The Quality Policy acts as the guiding principle for Laboratory management and staff, enabling the laboratory to sustain customer confidence in:
 - Operational integrity
 - Professional competence
 - Clinical and business judgment
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**Our
Commitment**

Our Commitment

The management and staff of the Sutter Health laboratories are committed to good professional practice and the provision of a high quality service that contributes to the health and well-being of our patients.

We work together to foster a culture of quality by placing the needs of our patients “at the center” of our work processes and all decisions that we make.

We actualize our commitment through the Laboratory Quality Management Program (QMP). The QMP provides the essential framework for managing the quality of all laboratory work processes, optimizing outcomes and ensuring:

- *Ethical business and professional conduct*
 - *Compliance with regulatory and accreditation requirements*
 - *An organization structure and scope of services that meet the needs of our patients*
 - *Continual improvement of our processes and outcomes*
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Quality Management Program, Continued

Overview

- In many ways, the Quality Manual can be thought of as the “Procedure Manual” for Managers and Supervisors because it provides the guidance and instructions for Managers and Supervisors to do their job (which is to provide employees with what they need to produce quality results)
 - But, there are programs and procedures in the Quality Manual that apply to and are carried out by laboratory staff such as:
 - Proficiency Testing Program
 - Hand-off Communication
 - Laboratory Safety Program
 - Proficiency Testing
 - Continuing Education Program
 - Laboratory Compliance Program
 - Laboratory management ensures the effective application of the quality procedures to all activities related to laboratory operations.
 - Laboratory management also ensures optimal integration of the procedures in the lab to affiliate and organizational quality and risk management programs.
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What is QA?

- Quality Assurance is a program that consists of guidelines designed to ensure accurate testing and reporting of results.
 - Laboratories must have an established QA program mandated by the Clinical Laboratory Improvement Amendments of 1988.
 - Accrediting agencies such as the CAP and TJC inspect to see if the quality program is effective
 - The QA program includes:
 - **Preanalytic phase:** covers all aspects affecting the test outcome prior to the testing procedure itself
 - Patient requisitions
 - Patient preparation
 - Specimen collection
 - Specimen transport
 - Specimen processing
 - Specimen storage
 - Staff training
 - Competency assessments
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Quality Management Program, Continued

- **Analytic phase:** incorporates all aspects of the testing procedure itself
 - Test methods/procedures
 - Reagents
 - Internal quality control
 - External quality control/proficiency testing
 - Instrument maintenance
 - Linearity/reportable range determination
 - Method evaluation/instrument comparison
 - Reference range determination
 - Personnel requirements
 - Staff training
 - Competency assessments
 - Continuing education
 - **Post-analytic phase:** covers all aspects affecting the test outcome occurring after the testing procedure
 - Review of patient results
 - Reporting patient results
 - Maintenance of patient records
 - Monitoring of turn-around time
 - Surveying of customer satisfaction
 - Maintaining all documentation
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QMP Goals

The goals of the QMP are to:

- Optimize internal and external customer satisfaction (physicians, patients and laboratory staff)
 - Optimize patient safety as defined by the CAP Patient Safety Goals
 - Ensure accreditation readiness at all times (CAP, TJC and IMQ)
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Where can you find the QME's?

The quality policies are found in PolicyStat. Go to the Sutter Intranet and log on to PolicyStat. You can then search by topic among all policies. For the North Valley labs, the quality policies are organized as one set of documents called the Quality Management Plan (QMP) and can be found in the Policy Area “Lab – Quality Management”.

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Quality Management Program, Continued

Elements of the QMP	The QMP is organized into 12 quality management essentials. These are listed below along with an example of a policy or standard within each.
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Quality Management Essential	Example
Documents and Records	Laboratory records must be kept for a defined period of time, the timing can be found in the Records Retention Policy
Organization	Defines various supervisory positions in the lab, including the Lab Medical Director who is ultimately responsible for the quality of lab services, but can delegate many functions to qualified staff
Personnel	There are federal (CLIA) and State (CDPH) rules defining when a license (ie CLS or MLT) is required to perform tasks in the laboratory, depending on test specialty and complexity.
Equipment	If equipment is malfunctioning, it must be tagged so that it is not accidentally used
Purchasing and Inventory	All Laboratory staff are responsible for proper inventory management, including visually checking contents of vials and containers to verify suitability before use, and removing expired, suspicious or questionable supplies from service and notifying Manager/Supervisor.
Process Control	Computer documentation of QC: all QC values (both in-control and out-of-control values), are to be entered into the lab LIS with appropriate documentation. See Sunquest (Misys) QC procedure under Quality Control Entry and QC Modifier Code Summary.
Information Management	The laboratory maintains a process for assigning staff access to the lab information system (LIS) based on the tasks the employee is legally allowed to perform.
Occurrence Management	The lab has a policy to document non-conforming events and a program for continual improvement which includes review of these events to prevent recurrence
Assessments – Internal/External	External assessments can be by accrediting agencies such as CAP or TJC, or by CMS, California state, FDA, OSHA or others
Process Improvement	Standardized forms and templates are used when possible to improve communication and provide better quality content
Customer Service	Clinicians and patients are surveyed on a regular basis to assess satisfaction and look for areas needing improvement
Facilities and Safety	The laboratory has specific policies for safety when applicable, but also follows affiliate and system safety policies

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**Training
requirements**

- Each staff member should access the quality documents for their location and review the quality policies applicable to their position.
- Each staff member must successfully complete ($\geq 80\%$) the “QMP quiz” which is a part of this module.
- Any questions about quality practices or policies should be referred to the supervisor or manager.

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