INTRODUCTION

A quality management system can be described as a set of key quality elements that must be in place for an organization’s work operations to function in a manner that meets the organization’s stated quality objectives. This system provides the means to direct and control the organization with regard to quality. The purpose of this Quality Manual is to define and document our facility’s quality management system. The Quality Manual communicates the structure and detail of our organization’s quality management and documentation systems to our own personnel, customers, and external assessors. The key quality elements used in the Department of Pathology and Laboratory Medicine’s Quality Manual are the following:

1. Organization
2. Personnel Resources
3. Equipment
4. Supplier and Customer Issues
5. Process Control
6. Documents and Records
7. Occurrence Management
8. Assessments
9. Process Improvement
10. Facilities and Safety
11. Information Management
12. Customer Service and Satisfaction

This quality management plan provides for continuous monitoring and evaluation of patient care activities within the Department of Pathology and Laboratory Medicine. Monitoring includes pre-analytic, analytic, and post-analytic phases of testing. The plan describes a standardized quality control system that maximizes the quality of laboratory testing to produce the accurate and timely results needed in support of quality patient care. The plan includes provisions for employee training and competency assessment, document control requirements, procedures for the monitoring of quality control, quality indicators, internal and external customer satisfaction, a process for systematic approach to occurrence management, processes for data access security and transfer integrity, and a formal departmental committee structure for the documentation and reporting of internal quality improvement activities. The plan was designed to maintain compliance with federal, state and local laws and regulations, as well as, organizational policies and ethical standards. Elements of this plan were developed after a careful risk assessment conducted by laboratory and hospital leadership.
SCOPE

This Quality Manual applies to the clinical sections of the Department of Pathology and Laboratory Medicine.

PROGRAM

Organization

The medical and administrative directors of the laboratory organized the staff into functional work groups. Each functional area of the laboratory is headed by a Manager and a Medical Director or Section Chief. The outline of the organizational structure is further described in QM 050, Introduction to the Department of Pathology & Laboratory Medicine, which is located in the next section of this manual.

New Employee Orientation

Employee orientation consists of a Hospital orientation and a Department Specific / Section Specific orientation. Newly hired staff must attend a hospital orientation within 45 days of hire and must complete Department Specific/Section Specific orientation within 30 days of hire.

New Employee Training

Employee training is section specific. Each section generates a training checklist(s) for each “competency” or job task the employee will be trained to perform. The completed training checklists are signed by the employee, trainer, and section supervisor. This checklist becomes part of the employee’s Department training record. In some sections, the preceptor training model is used; in others, the employee rotates through assigned blocks and is trained by a senior technologist. Employee performance is reviewed 6 months post hire and annually as part of the performance evaluation (PE) process.

Competency Training and Education

The Department has an internal program of continuing education (journal articles, teleconferences, lectures) and evaluation of competency (direct observation, worksheet review, CAP proficiency sample performance). In addition, the laboratory provides for competency training with regard to age-specific competency, as appropriate, and laboratory safety. Initial and Annual competency assessments are documented on Initial/Annual Validation Summary forms and are signed by the employee, trainer, and section supervisor. The competency validation forms become part of the employee’s personnel record.

Equipment

The laboratory has policies, processes and procedures for the selection, acquisition, installation, validation, periodic maintenance and quality assessment of equipment critical to
the provision of services in the Department. Each piece of equipment is uniquely identified; calibration, maintenance, and monitoring conform to specified requirements. In addition, the laboratory maintains a process to investigate and follow up equipment malfunctions, failures, or adverse events. Prior to disposal or release to surplus inventory, equipment that may have been in contact with chemical, biohazardous or radioactive substances is decontaminated and decommissioned.

**Supplies**

The laboratory administrative and technical staff are responsible for supporting laboratory operations with an uninterrupted flow of material and services. The objective of the laboratory is to acquire materials of the right quality, the right quantity, the right time, from the right supplier and at the right price.

**Referral Laboratories**

The laboratory medical director, in consultation with UCLA Medical Center and client clinicians (as appropriate), selects referral laboratories based on, but not limited to, quality, methodology, and accreditation status (a high complexity CLIA license is mandatory, CAP accreditation desirable). The Laboratory Medical Director monitors the quality of test results by annually reviewing a sampling of results as they are received in the laboratory. Reference laboratories are also reviewed and approved by the medical staff. A complaint by a physician concerning a test sent to a referral laboratory is referred to the Laboratory Medical Director and an investigation is initiated with the referral laboratory.

**Procedure Quality Control**

Quality Control (QC; sometimes called process control) is the analysis of materials of known composition or reactivity in conjunction with patient sample testing to verify the performance of a test. QC materials are “pseudo-samples” designed to detect problems in instrument, reagent, software, or analyst performance. QC is predominantly a measure of precision (reproducibility) and confirms that a test system has maintained proper calibration.

For some analytes, the control material is a manufactured, purchased control product supplied in either a lyophilized or liquid form; the concentration has been both gravimetrically and analytically determined prior to distribution of the product. These materials must be evaluated in-house to determine the laboratory mean, standard deviation, and coefficient of variation before placing into service. This data is collected while running in parallel with the control product currently in use. There are some analytes that are not available in commercial preparations; hence they are prepared in the laboratory to create an appropriate control for the assay method performed. These materials must be evaluated in the same fashion as commercial products prior to placing in service.
The management of quality control occurs on a real-time basis and as a continuous tool in evaluating the reliability of test data. Technologists, supervisors, managers, and laboratory directors all contribute to this review process on a daily, weekly, and monthly basis.

The frequency of control analysis, and the preparation, reconstitution, storage conditions, and stability of specimens and reagents are described in individual procedures for each type of test. The tolerance limits for controls are established by individual sections. Values which fall outside these ranges must be evaluated according to the internal control rules used in individual sections. Violation of the QC rules results in review by the supervisor and/or director and may result in rejection of the analytical run. The run must be inspected to determine the cause for error. After solving the problem that caused the QC exception, the entire run may need to be repeated, along with QC evaluation. Quality control records are maintained for a minimum period of 3 years (5 years for Transfusion Medicine).

**Proficiency Testing (PT)**

Proficiency testing is defined as periodic testing of samples whose composition or reactivity is unknown to the laboratory. PT samples are usually provided by an external agency that “knows” what an analytic result is expected to be or establishes the “correct” answer based on aggregate results from large numbers of laboratories participating in the survey.

In the clinical laboratory, each section (as appropriate) is enrolled in a CMS-approved proficiency testing program for all tests for which CAP or other CMS approved proficiency testing is available. Results are evaluated by the survey provider against peer group responses. Internally, results are reviewed by the section supervisor or laboratory manager and the laboratory director. Outliers are investigated, corrective action is taken, and a report is made to the Quality Oversight committee based on the criteria set forth below.

Survey samples are to be integrated within the routine laboratory workload, and the samples analyzed by personnel who routinely test patient samples, using the same methods. The educational purpose and documentation of proficiency is best served by a rotation that allows all technologists to be involved in the proficiency testing program. Replicate analysis of survey samples is acceptable only if patient specimens are routinely analyzed in the same manner.

In accordance with CMS regulations, laboratories are forbidden to “engage in any inter-laboratory communications pertaining to the results of proficiency test samples” or to “send PT samples or portions of samples to another laboratory for analysis.”

For analytes where graded proficiency testing is not available, performance must be checked at least semiannually using an alternate performance assessment system. These procedures include participation in ungraded proficiency survey programs, split
sample analysis with reference or other laboratories, split samples with an established in-house method, certified materials, regional pools, clinical validation by chart review, or other suitable documented means. It is the responsibility of the laboratory section director to define such procedures, as applicable, in accordance with good clinical and scientific laboratory practice.

If laboratory testing of a PT challenge does not produce acceptable results, the cause of the error must be investigated and corrected. There are several types of errors: methodological (the source is within the analytic system); technical (the source is attributable to performance within the laboratory); clerical (errors made in completing the forms returned to the surveyors for processing, such as transcription errors); survey (errors attributed to the survey materials or to the directions accompanying the survey material, such as matrix effects, unstable survey samples, a validated deviation from the consensus, or survey samples that did not arrive on time); or unexplained. An error should be designated as unexplained only after a full investigation has been completed, eliminating every other possibility of error.

**Document Control**

Each section supervisor and director is responsible for ensuring that policies and procedures for the section are current, that appropriate revisions occur annually or more often, as needed, and that each technologist is kept abreast of procedural changes through a method change notification or technologist procedure sign off. New method procedures require director or designee signature prior to implementation. Procedures must be retained for a minimum of 3 years after discontinuation (10 years for Transfusion Medicine). Each section should establish a system for document management, review, and retention.

**QA Monitoring**

Each laboratory section has identified indicators to monitor quality of operations. Indicators may be pre-analytic, analytic, or post-analytic. An effort has been made to select indicators that support the CAP patient safety goals. When appropriate, trends are evaluated over time to evaluate deviation from baseline. Regular reports are made to quality assurance committees regarding performance and improvement opportunities. Refer to Supplemental Materials for a list of quality metrics.

**Occurrence Management**

The laboratory is actively involved in capturing and analyzing information from nonconforming events to identify systematic laboratory problems, both internally and externally. The following methods are used to detect errors:

- **Random Review** Error detected within laboratory section by predetermined internal review processes (internal).
- **Laboratory Detection** Error detected by means other than a random review (internal).
External Detection Error reported by a physician, nurse, or other customers/individuals outside the laboratory (Event Reporting System).

Each laboratory section is responsible for capturing/developing a system for detecting errors using all three of the above methods. A summary of laboratory occurrences (including trends) is reviewed at the Quality Oversight Committee on a quarterly basis.

**External Inspection/Accreditation Assessment**

The laboratory participates in the College of American Pathologists (CAP) Laboratory Accreditation Program (LAP). The accreditation process from CAP includes an unannounced inspection by a team of professionals from a peer organization every two years. During the two year cycle, the Medical Director is responsible for assembling a team to provide inspection services for another laboratory similar in size and complexity to UCLA. The Manager of Regulatory Affairs is responsible for all inspection submissions and oversees compliance with the certification requirements (refer to QM 805 for terms of accreditation).

Sections of the laboratory undergo additional external inspections as listed below.

**Transfusion Medicine**
- Food and Drug Administration, unannounced, variable
- AABB, unannounced, every two years
- State of California Biologics, unannounced, every three years
- Foundation for the Accreditation of Cellular Therapy, scheduled, every three years

**Brentwood**
- Center for Disease Control Select Agent Program, unannounced

**Immunogenetics**
- American Society for Histocompatibility and Immunogenetics, unannounced

The Medical Center is accredited by the Joint Commission (JC). JC accepts the CAP accreditation for the laboratory-specific portion of the standards. The laboratory supports UCLA Health System’s efforts to comply with JC hospital accreditation standards.

**Performance Improvement**

The quality program of the Department currently includes a number of performance improvement initiatives for important laboratory services. Each laboratory section is responsible to select PI initiatives to improve performance. There is an assigned PI reporting schedule; division reports are reviewed quarterly at the Quality Oversight meetings.
Interdisciplinary Activities

Committee involvement by faculty and staff demonstrates integration of laboratory and hospital quality management programs. Laboratory representatives serve on the following hospital-wide quality committees:

**Westwood/Brentwood:**
- Antibiotic Subcommittee
- Environment of Care Committee
- Medical Staff Executive Committee
- Transfusion Review Committee
- Laboratory and Nursing Communication Strategy Committee
- Performance Improvement & Patient Safety Committee
- Infection Control Committee
- Hospital Compliance Committee
- Point of Care Testing Committee
- Emergency Medicine Committee
- Clinical Laboratory Activities Committee
- Hospital Operations Team
- Infection Control Committee
- Radiation Safety Committee
- Ambulatory Care Managers
- Incident Management & Response Team – Medical Plaza
- Operating Room Committee

**Santa Monica:**
- Joint Committee Functional Team
- Infection Control Committee
- Nursing Outcomes Committee
- Patient Safety and Identification Committee
- Patient Satisfaction Committee
- Environment of Care Committee
- Disaster Committee
- Hazmat Committee
- Operations Council
- Transition Team
- Point Of Care Committee
- Management Forum
- Cancer Committee
- Medicine Committee
- Surgery Committee
- Surgical Case Review Committee
Safety and Facilities

The laboratory has designed and organized its quarters, environment, and equipment, and implemented appropriate processes to minimize and respond to environmentally related risks to the health and safety of employees, donors, volunteers, patients, and visitors. A Department safety committee meets 6 times a year in order to:

- Keep all sections of the laboratory current with safety related information;
- Ensure safety related tasks are occurring on schedule;
- Review revised safety regulations, policies, and training materials;
- Conduct safety related performance improvement initiatives;
- Address safety concerns;
- Clarify safety policies;
- Evaluate incident and accident reports for the Department;
- Review and evaluate the effectiveness of the laboratory’s Chemical Hygiene Plan; and
- Make recommendations to Executive Management related to safety policies.

The Department strives to proactively address patient safety concerns; safety goals are evaluated and monitored annually.

Information Management

The Department has policies and procedures for data access security and transfer integrity. Access to the laboratory information system, Meditech, is limited to authorized users by various security measures which include, but are not limited to:

- Computer menus to which the user is assigned based on job responsibility
- Access level groups
- User profiles
- Operator codes
- User identification codes
- Passwords.

Division Medical Directors, the Clinical Laboratory Director of Operations, the Data Security Officer and/or Systems Manager must approve authorization of users. The system has security standards designed to restrict unauthorized direct or remote data access and the ability to identify individuals responsible for the assault.

All computer network connectivity is maintained in a secure environment following both the University and hospital policies with the use of:

- Anti-virus protection
- Anti-spyware protection
- Operating system critical patch updates.
System vital checks are verified quarterly and/or following any scheduled or unscheduled computer downtime as a method to verify:

- Integrity of stored data
- Access criteria remains intact
- Security continues to function as required.

Annually, a summary report is prepared to validate the integrity and accuracy of data transmission (patient verified results compared from point of entry to computer screen, paper printouts and electronic reports as an audit).

A risk assessment and validation of the computer system is performed as required by regulatory agencies for all changes or upgrades. Each department is responsible for the development, training and practice of computer downtime procedures.

The laboratory complies with all HIPAA regulations related to the privacy and confidentiality of patient information. The laboratory periodically monitors compliance by auditing current laboratory practice.

**Customer Service and Satisfaction**

Referring physicians and nursing staff are asked to provide input on areas of laboratory improvement ranging from STAT/routine test turnaround times, the reliability of results, critical value notification, phlebotomy services and test menus to the courtesy/helpfulness of laboratory staff and faculty; the customer satisfaction surveys are conducted no less than every 2 years.

The hospital conducts periodic employee satisfaction surveys patterned around the following themes:

- Improved communication
- Enabling work/life balances
- Developing support systems for the staff
- Enhancing rewards and recognition
- Creating a culture of excellence.

Survey results are analyzed and process improvement projects are developed when the situation or services require remediation.

Globally, hospital Patient Relations oversees customer complaints. Internally, the laboratory captures patient/donor issues through the Occurrence Management process. Volunteer Services tracks patient satisfaction through the C-ICARE program.

As required by regulatory agencies, processes and procedures are in place for client notification related to manufacturer recall or commercial service issues.

**Commitment to Quality, Safety, and Integrity**
The laboratory is committed to a culture of quality, patient safety, and organizational integrity. Management and staff should comply with established performance standards, controls, discipline, and structure. All employees are encouraged to discuss quality, patient safety, and other concerns without fear of retribution.

**Quality Oversight**

The Department of Pathology and Laboratory Medicine’s quality management plan is overseen by the Quality Oversight Committee. Oversight Committee meetings are scheduled quarterly for:

- The CORE laboratory (includes Special Chemistry), Support Services, Transfusion Medicine, Microbiology/Cytogenetics and Computer Services;
- Anatomic Pathology (all sections); and
- Santa Monica Hospital clinical laboratories.

Chairs: Linda Baum, M.D., Medical Laboratory Director
      Scott Nelson, M.D., Medical Laboratory Director
      Ann Shadler, Manager of Regulatory Affairs

Each laboratory section is represented by a laboratory supervisor and/or director or their designee. Minutes are recorded, electronically transmitted, and reviewed; the approved copies are retained in the Office of Regulatory Affairs. The laboratory Quality Oversight Committee will:

- Review personnel tracking reports from the hospital’s compliance tracking system;
- Review proficiency testing;
- Review internal and external laboratory incident reports;
- Review corrective action taken as a result of the quality improvement findings;
- Review other QA reports, as submitted; and
- Identify and implement programs for continuous quality improvement.

**Quality Planning**

The objectives, organization, comprehensiveness, and effectiveness of the laboratory quality management program are evaluated at least annually, and the program revised as necessary. This evaluation is performed by the Manager of Regulatory Affairs or designee and approved by the Laboratory Medical Director(s) and Director(s) of the Laboratory Operations. The evaluation is shared with the management team. Focus will be placed on areas of technological change and organizational change, as well as recurring problems.

**REFERENCES**

• California State Laboratory Regulations and Statutes.
• Code of Federal Regulations, Title 49, Part 493
• Quality Management In Clinical Laboratories, CAP, 2005
• Laboratory Accreditation Manual, most current copy, College of American Pathologists, 325 Waukegan Road, Northfield, IL, 60093.
• The Key to Quality-Fundamentals for Implementing a Quality Management System in the Clinical Laboratory, CLSI, 940 West Valley Road, Suite 1400, Wayne Pennsylvania, 19087, 2006.
• Standards for Blood Banks and Transfusion Services, most current edition, AABB, Bethesda, Maryland.

SUPPLEMENTAL MATERIALS
• QM 020.1 Quality Metrics – Clinical (Westwood)
• QM 020.2 Quality Metrics – Santa Monica
• QM 020.3 Quality Metrics – Anatomic Pathology (Westwood)