

Significant events are investigated promptly and include, but are not limited to:

- patient, visitor, donor, and/or employee safety incidents
- risk management issues, i.e., sentinel events
- departmentally defined issues
- proficiency testing failures
- customer service issues

Events are categorized and evaluated for trends, patterns, and other useful information. Quality improvement tools are used in determining appropriate corrective action. The improvement process is initiated when needed.

Assessments

We participate in both internal and external assessments. We have a documented process for conducting:

- internal assessments of our operations and the quality system
- internal quality indicator measurements
- proficiency testing

In addition, we participate in external assessments that include but are not limited to:

- regulatory inspections
- accreditation assessments
- clinical trial assessments

Process Improvement

We are continuously improving the processes and services that support our mission for clinical practice, education, and research. Sources of information to identify opportunities for improvement include but are not limited to:

- customer surveys and complaints
- event trends and patterns
- risk management issues
- quality indicator data
- findings from external assessments
- findings from internal assessments
- new or revised regulatory/accreditation requirements

Process improvement efforts utilize quality management tools to determine appropriate remedial, corrective, and preventive actions. Quality management tools include,

but are not limited to the following:

- four-step Continuous Improvement (CI) process
- project management process
- process improvement teams
- Six-Sigma/Lean improvement process
- root cause analysis process
- statistical methods (e.g., Pareto charts, control charts, histograms)
- non-statistical methods (e.g., brainstorm, cause and effect diagrams, root cause analysis)

Service and Satisfaction

We determine customer needs, provide for customer feedback, and use this information in the design, implementation, and evaluation of our products and services.

Customers are surveyed to determine what they will need from our organization. New or changed processes, products, and services are designed to meet the needs of our customers.

Customer satisfaction surveys are conducted for both internal and external customers. Action plans are created based upon survey results to guide activities in the future.

Facilities and Safety

We provide an adequate and safe environment that meets federal, state, and local regulatory and accreditation requirements. We provide safe environmental conditions for staff, donors, patients, and visitors. All staff is provided with opportunities for training in safety programs. We work with our Facilities Management Department on facilities design, construction, and maintenance.

A Contingency Plan exists that describes the actions taken during an unforeseen event. The plans for each work area are developed to guide responses to situations that may impact services and to avoid significant disruption to services. For further questions concerning Framework for Quality, please call 1-800-541-5815.

Framework for Quality

Mayo Clinical Trial Services

Mayo Department of Laboratory Medicine and Pathology

Mayo Medical Laboratories

Framework for Quality is the foundation for the development and implementation of the quality program for Mayo Clinical Trial Services, the Mayo Department of Laboratory Medicine and Pathology, and Mayo Medical Laboratories.

Our framework builds upon the concepts of quality control and quality assurance providing an opportunity to deliver consistent, high-quality, and cost-effective service to our clients.

Framework for Quality is composed of eleven Quality System Essentials. The policies, processes, and procedures associated with the Quality System Essentials can be applied to all operations in the path of workflow (e.g., pre-analytical, analytical, and post-analytical). Framework for Quality is managed with a focus on continuous quality improvement.

“It has become necessary to develop medicine as a cooperative science; the clinician, the specialist, and the laboratory workers united for the good of the patient, ... and each dependent upon the other for support.”

William J. Mayo, M.D.

Framework for Quality enhances our ability to meet and exceed the requirements of regulatory/accreditation agencies and provide quality service to our customers. The following outlines aspects of the Quality System Framework:

Quality System Essentials

Organization

- Organization Structure
- Mission
- Leadership Review
- Resources

Personnel

- Job Qualifications
- Job Descriptions
- Orientation & Training
- Competency
- Continuing Education

Equipment

- Selection & Acquisition
- Installation Qualification
- Operations & Calibration
- Maintenance & Repairs

Purchasing and Inventory

- Critical Materials & Services
- Qualification of Suppliers
- Maintenance of Inventory
- Market Recall

Process Control

- Validation
- Process Monitoring
- Quality Control
- Change Control

Documents and Records

- Document Creation
- Change Control
- Annual Review
- Numbering & Master Index
- Record Quality & Review
- Retention, Storage, & Retrieval

Event Management

- Detection, Documentation, & Investigation
- Categorization & Analysis

Assessment

- Quality Indicators
- Internal Assessments
- External Assessments
- Proficiency Testing
- Quality Reporting

Process Improvement

- Opportunities for Improvement
- Quality Management Tools

Service and Satisfaction

- Surveys
- Customer Comments
- Consultations
- Needs Assessments

Facilities and Safety

- Safety Programs

Organization

Mayo Clinical Trial Services, the Mayo Department of Laboratory Medicine and Pathology, and Mayo Medical Laboratories have a quality system that provides a mechanism for compliance with regulatory and accreditation requirements and guidance for the provision of services. The quality system provides a planned, systematic program for defining, implementing, monitoring, and evaluating services to our customers. We have a defined process for both quality planning and evaluating the effectiveness and efficiency of the quality system through scheduled leadership reviews.

Our leadership is committed to and supports all activities inherent in the establishment, participation, and implementation of the quality system. Quality assurance personnel and leadership are responsible for implementing and maintaining the quality system. The work units support the quality system and contribute data for quality reports.

Personnel

We set qualifications for job functions, hire and train qualified personnel, and assess competence in job tasks.

We participate in Mayo organization's performance appraisal process.

Job descriptions are maintained for each job function. Job qualifications (e.g., prerequisite education, credentials, experience, and skills) are specified for each job function.

New employees receive orientation to the organization and specific departments. Training is provided to employees:

- when hired
- for new or changed processes or procedures
- as training needs are identified

The competency of employees is assessed both after training and in scheduled reviews. The outcome of orientation, training and competency assessments, continuing education, and performance appraisals is documented.

Equipment

We follow the established Mayo organization processes for acquiring equipment. The selection process is based on defined and documented equipment requirements. Newly acquired equipment is identified and undergoes installation qualification, initial calibration, and process validation. Appropriate documentation is maintained.

Equipment is operated according to the manufacturer's instructions. Calibration and preventive maintenance of equipment is performed using documented procedures per an established schedule based on regulations, accreditation requirements, and manufacturer's instructions. Repairs are performed as needed and all calibration, maintenance, and repairs are documented.

Purchasing and Inventory

We provide a mechanism in which we control reagents, supplies, and qualify reference laboratories.

Qualification of suppliers is performed by a defined process that includes:

- establishing criteria that suppliers must meet for identified critical materials and services
- assessing supplier performance
- agreements/contracts that are signed with suppliers and reviewed periodically

Materials that are essential to providing tests and services are identified and a list of these materials is maintained.

Actions are taken when notification of a material recall is received.

Qualification of reference laboratory services is performed by a defined process that includes:

- selecting the reference laboratory based on established criteria
- periodic assessment of the laboratory's performance

Process Control

We have documented processes to:

- define and validate processes
- perform procedures and document outcomes
- monitor procedures (e.g., quality control, proficiency testing, quality indicators, etc.)
- control changes for the quality system essentials and operations in the path of work flow

We identify necessary processes or process changes based on customer needs and regulatory/accreditation requirements:

- processes are designed, developed, and documented
- procedures are identified and written
- validation protocols are developed
- validation is conducted and documented

All employees must follow procedures for performing their work and creating necessary records.

Documents and Records

Documents and records are developed, managed, and controlled according to regulatory and accreditation requirements. We determine which documents will be controlled but at a minimum will include policies, process documents (e.g., flowcharts), procedures, guidelines, and forms.

The document management process requires that:

- standardized formats are established
- there is established authority to write, revise, review, and approve documents
- unapproved changes are not made to documents
- the most current versions of documents are available at all locations where the corresponding critical processes are performed with sufficient access to meet the needs of the users
- review of each document occurs at least annually by authorized individuals
- master documents of current versions and obsolete documents are protected from inadvertent destruction
- obsolete documents are archived per organizational record retention guidelines
- records of review that are clearly traceable to applicable documents are created and maintained

We have defined a record management process. This process requires that records are:

- retained per established departmental guidelines
- retrievable within a reasonable time period
- protected from inadvertent destruction and unauthorized access
- discarded when appropriate (e.g., after the retention period expires)

Event Management

We detect and document events; investigate, categorize, and analyze event information; and take appropriate improvement measures. The information about discrete events is captured and investigated to identify system issues that require improvement measures.