Name of Policy: **Quality System Essentials** **Policy Number**: 3364-108-001 **Approving Officer**: Medical Director, Clinical Pathology **Responsible Agent**: Administrative Director, Laboratory **Scope**: University of Toledo Medical Center, Pathology Laboratory	**Effective date:** 03/2025 **Original effective date**: 10/1994
Key words: Quality system, policies and procedures, quality assurance and quality control, personnel qualifications, quality reviews.	

☐	New policy proposal	☒	Minor/technical revision of existing policy
☐	Major revision of existing policy	☐	Reaffirmation of existing policy

(A) Policy Statement

The quality system supports the ideals set forth in the mission statements of the University of Toledo Medical Center and Laboratory. The quality system is organized to monitor processes and operations in the Core Lab of the University of Toledo Medical Center Laboratory through the performance of self-assessment audits, error management, and customer feedback. By conforming to regulatory standards, we abide by the law. By conforming to requirements for accreditation, we adhere to high standards for quality established by the College of American Pathologists and other peer-review organizations. By conforming to our customer's standards, we practice the philosophy of continuous quality improvement.

(B) Purpose of policy

To ensure that The University of Toledo Medical Center (UTMC) Laboratory maintains a quality system that conforms to the minimum requirements of FDA, CAP, and other accrediting organizations. The essentials of the quality system are described in further detail in this document.

(C) Procedure

Organization

1. UTMC Clinical Laboratory's organizational relationships are found in the department's organization chart maintained by the department's Administrative Director.

2. The goals of University of Toledo Medical Center Laboratories are to provide high quality testing and services by:

- Detecting and preventing errors in testing processes.
- Reducing process variations that can cause errors.
- Improving effectiveness and efficiency of processes.
- Responding to customer needs in provision of testing and services.
- Developing and maintaining competent staff.
- Complying with all required regulations and accreditation standards.

3. Management support for the quality system
    - Hospital Administration designates a responsible head for oversight of Hospital PI committee, Lab Utilization Review committee and other inter-disciplinary concerns.
    - The Clinical Laboratory medical director is responsible for monitoring and evaluating activities specific to the Clinical Laboratory.
    - The administrative director/lab manager is responsible for Pathology quality assessment monitoring and evaluation.
    - The Clinical Laboratory supervisor/manager is the designated quality person and has oversight/responsibility for monitoring and evaluating Clinical Laboratory activities and reporting findings to Medical Director, Clinical Lab Director, Lab Supervisors, and administration.
    - Clinical Laboratory personnel assist in monitoring daily activities and specific audits/ quality procedures.
4. Review and approval of the quality policies and quality essential process descriptions
    - The quality policies are initially approved by the Clinical Laboratory medical director and reviewed biennially by the manager/coordinator/supervisor.
    - The quality essential process descriptions (procedures) are approved by the Clinical Laboratory medical director and reviewed biennially by department managers/supervisors.
    - Quality policies are approved and reviewed biennially by Lab Administration. Quality policies are reviewed periodically by Hospital Administration and interdisciplinary committees (i.e. Quality and Safety, Nursing leadership, Medical Executive, Lab Utilization Review committee).

Personnel

This facility employs qualified individuals who meet the education, training and experience necessary to perform assigned tasks as defined in job descriptions.

1. Job descriptions and employee qualifications
    - Job descriptions are written and maintained for each position.
    - To be considered for hire, candidates must meet the qualifications (education and/or experience) stated in the job description.
    - The candidate must provide documentation of education, training, and experience.

2. Orientation
    - New employees are provided orientation to the organization, department, and specific job for which they are hired.

3. Training
    - Training is provided as required per job description expectations and includes training related to specific job requirements, safety, computer, personal development, quality, and other skills as needed.
    - Staff development is provided to meet individual needs, regulatory and accreditation requirements, and the changing needs of the facility.
    - Training is considered completed when the individual demonstrates sufficient knowledge and skills for the job and can work independently.
    - Retraining is initiated when indicated.
    - Documentation of training and initial competence is maintained.

4. Assessment of competence
    - Staff competence is initially determined during job task training.
    - Ongoing competence is assessed at six months and one year and then at least annually thereafter by written or verbal testing, direct observation, and work review.
    - Documentation of competence assessment is maintained.

5. Continuing education
    - Continuing education by the various means available is encouraged.
    - Documentation of continuing education is maintained.

6. Performance appraisal
    - A performance review based on job accountabilities, objective measures, and pre-defined standards is completed for each employee, documented, and maintained.

7. Trainer qualification
    - All staff meeting annual competency requirements may function as trainers in the Clinical Laboratory.

Equipment

1. Selection
    - A process to identify specifications for new equipment is maintained, where appropriate.
    - The specifications are shared with suppliers, where appropriate.
    - The suppliers' ability to meet the specifications and other criteria are considered in the selection process, where appropriate.

2. Installation
    - Installation is performed by a documented plan/procedure.
    - The supplier may take an active role in the installation process.
    - The equipment is properly installed and tested as part of the validation protocol.

3. Calibration

- All measurement devices, new or repaired, used in critical processes are calibrated according to procedures written in accordance with manufacturer's recommendations, regulatory requirements, and accreditation standards.
- Complete documentation of equipment identity, results of scheduled calibrations, actions taken, and disposition of the equipment is maintained.

4. Preventive Maintenance
    - Preventive maintenance schedules are determined by manufacturer's recommendations, regulatory requirements, accreditation standards, and internal requirements.
    - Documentation of maintenance includes findings, actions, and follow up.

5. Defective Equipment
    - Defective equipment is identified, controlled, and repaired or replaced.

Supplier Issues

1. Supplier Qualification
    * The University of Toledo Medical Center Clinical Laboratory has:
        - defined the characteristics or functional requirements for critical materials, blood and blood components, products, or services.
        - assessed both the ability of our suppliers to meet our requirements and their actual performance.

2. Contract review
    - Agreements to obtain blood and blood components, products, and services are reviewed to ensure that each party's expectations are defined and agreed to and that any changes are appropriately recorded and communicated.

3. Receipt, Inspection, and Testing of Incoming Supplies
    - There is a process for receiving, inspecting, and testing (where required) incoming critical materials, blood and blood components and products.
    - Criteria have been established for accepting critical materials, blood components and products.
    - Critical materials, blood components and products not meeting acceptance criteria are quarantined.
    - There is a process to ensure traceability and storage of critical materials, blood components and products prior to use.
    - All critical reagents and testing materials are properly labeled with contents, concentration, titer, storage requirements, preparation, and expiration as appropriate.

Process Control, Final Inspection, and Handling

The University of Toledo Medical Center's Clinical Laboratory utilizes process control measures that include:

1. Development and use of standard operating procedures

- Written procedures for operational tasks and policies initially approved by Medical Director.

2. Change control
   - A process exists to change established processes and/or procedures. Such changes are documented and approved by the Medical Director.

3. Information Systems, computers, and software
   - User acceptance activities are performed for new or revised software.

4. Process validation for new or changed processes or procedures.
   - Validation activities include equipment installation and documentation that the process works as intended before actual use.
   - Revalidation is performed when changes occur that could affect the outcome of a process.
   - Written validation protocols are used for all validations.
   - Retrospective validation is performed for well-established processes using historical data, when appropriate.
   - Validation results are reviewed and approved prior to process implementation.
   - Results of all validation activities are documented.

5. Use of labels and the labeling process
   - A process is maintained for all activities related to labeling blood components, beginning with the selection or design of a label, and finishing with its placement on the blood component.
   - An example of labeling protocol is maintained for applicable components.

6. Proficiency testing
   - Proficiency testing (PT) measures and compares testing systems of the University of Toledo Medical Center Clinical Laboratory with the outcome of testing performed by other laboratory peers.
   - The University of Toledo Medical Center Clinical Laboratory participates in proficiency testing programs appropriate for its level of testing.
   - The PT program includes designation of testing personnel, frequency of challenges, routine review, and corrective action.

7. Quality control (QC)
   - Established schedules for QC of equipment, reagents, and blood components are maintained and followed.

8. Process and product specifications.
   - Specifications are determined from manufacturers' instructions, regulations and accreditation standards and are incorporated into their respective procedures.

9. Non-conforming blood and blood components and products
   - The means to identify and handle these are incorporated into their respective procedures.

10. Final inspection and testing
    - Criteria have been developed for the release of finished blood or blood components, products, or services, including blood availability and turnaround time for critical services.

11. Handling, storage, distribution, and transport
    - Storage requirements for in-process and finished blood components and products are maintained and followed.
    - Packing requirements for transportation have been developed.
    - There are methods to trace any blood component or product distributed, issued, or returned.
    - There is a process to investigate (where applicable) and dispose of returned blood and blood components and products.

Documents and Records

1. Document control
   The University of Toledo Medical Center Clinical Laboratory maintains:
   - A structure to link its policies, processes, and procedures.
   - A process to ensure uniformity of standard operating procedures and forms.
   - A process to:
     - Review and approve new documents that include QA and management when applicable.
     - Biennial review of existing documents by designated staff.
     - Control of document versions and effective dates.
     - Review and approve document changes that includes QA and management when applicable.
     - Control document distribution and obsolete documents.
     - Archive and protect obsolete documents.

2. Generating, reviewing, retaining, and retrieving records
   - Formats and content of records are defined in respective standard operating procedures (SOPs).
   - Records are generated according to instructions in related SOPs.
   - Regulatory requirements and accreditation standards are used to determine what records are reviewed and the review schedule.
   - Records are retained according to regulatory requirements, accreditation standards, and internal specifications.
   - Records are stored in a manner that maintains their integrity and facilitates their retrieval.

Incidents, Errors, and Accidents

1. Reporting, classifying, analyzing
   - The University of Toledo Medical Center Clinical Laboratory maintains a mechanism to document and investigate events that could affect the quality and safety of blood, blood components, products, and services. Where appropriate, events are further classified, analyzed, and monitored for trends.

- A process exists for personnel to anonymously communicate concerns about quality or safety to executive management or CAP.

2. Corrective and preventive action
   - Action is taken to eliminate the root cause(s) of existing problems to prevent recurrence.
   - Corrective actions are monitored for effectiveness.

3. Tracking and trending
   - A log of events is maintained to ensure that the steps taken in resolving a problem are documented.
   - Trend analysis of incidents, errors, and accidents is performed to aid in prioritizing process improvement efforts.

4. Management review and impact
   - Event reports are submitted to management for review and approval of corrective action.

5. Regulatory agency notification
   - A system exists to determine whether an error/event is reportable to the FDA.
   - There is a procedure for reporting errors to the FDA.
   - Adverse events involving medical devices are reported to the FDA per institutional policy.

6. Failure to meet specified requirements
   - There is a process to identify, separate, and document critical material failures at the time of:
     - incoming inspection
     - inventory handling
     - distribution or issue.

Assessments: Internal and External

1. External assessments
   - The University of Toledo Medical Center Clinical Laboratory participates in external assessments conducted by the FDA or CMS where required.
   - The University of Toledo Medical Center Clinical Laboratory participates in the voluntary external assessments required of the Joint Commission, CAP, and ASHI accreditation programs, as applicable.
   - A process is maintained to conduct, report, and follow-up on external inspections, assessments, or investigations.

2. Operational self-assessment
   - The University Medical Center Clinical Laboratory has identified its applicable operational systems, encompassing pre-analytic, analytic, and post-analytic activities. They are:
     - Pre-Analytic: Specimen Collection, Identification and Handling; Test requisition
     - Analytic: QC, Tolerance Limits and Testing
     - Post-Analytic: Resulting, including Turnaround time, correction of results and Physician Notification of critical and corrected results

    - Blood component wastage and appropriate use and handling of blood and blood products
    - Blood culture contamination rates
    - Record and Specimen Retention and Storage
  - Procedures are in place for Clinical Laboratory personnel to capture data on quality indicators for the operational systems defined above, including indicators to monitor specimen identification, test requisition, corrected results, critical result notification, turnaround times and accuracy of reports.
  - The University of Toledo Medical Center maintains a system of planned and documented internal audits to improve quality that:
    - Ensures operational systems meet regulations and standards.
    - Determines the effectiveness of the quality system.
    - Provides a basis for quality improvement.
    - Meets the needs of interdisciplinary hospital Quality/Patient safety monitors.
  - Activities with an emphasis on CAP Laboratory Patient Safety Goals:
    - Improve patient and sample identification at specimen collection, analysis, and result delivery.
    - Improve verification and communication of life-threatening or life-altering information regarding malignancies, HIV (and other serious infectious diseases), cytogenetic abnormalities and critical results.
    - Improve identification, communication, and correction of errors in a timely manner.
    - Improve the coordination of the laboratory's patient safety role within healthcare organizations (nursing, administration, POC personnel, providers).

3. Periodic reporting
   - Individuals with quality assurance responsibilities compile results of self-assessments of operational systems into summary reports.
   - Formal reports detailing the findings, results, and any identified problems are prepared and communicated to appropriate staff, Lab Utilization Review committee and Hospital PI committee when appropriate.
4. Tracking and trending
   - Results of current assessments are compared to previous results.
   - Trend analysis is performed to aid in prioritizing process improvement efforts.

5. Follow-up
   - Follow-up is performed to determine the effectiveness of any changes or corrective action.

6. Management involvement
   - Summary and formal reports are submitted to management through the Hospital PI committee and the Lab Utilization Review committee for review and comment. Laboratory representatives participate in interdisciplinary hospital committees to address National Patient Safety Goals.

Process Improvement

1. The following serve as a source for process improvements activities:

- External assessment report findings (FDA, TJC, CAP).
- The findings from quality indicators of operating systems and internal quality audits.
- Reports of customer complaints and service rating surveys.
- Analysis of incident, error, accident reports.
- Review of any selected process to determine if the process can be made more efficient and effective.

2. University of Toledo Medical Center Clinical Laboratory uses an approach to problem resolution that includes:
   - Identification, prioritization, and selection of problems to be resolved.
   - Use of data collection and data analysis tools.
   - Implementation of process changes, where appropriate.
   - Evaluation of applied solutions for effectiveness in solving the problem.

3. Statistical tools to analyze numeric data are used where appropriate.

Facilities and Safety

1. As part of the hospital's mandated environmental control program, procedures are maintained and training is provided and documented for:
   - Emergency preparedness.
   - Chemical hygiene ("right to know").
   - Bloodborne pathogens.
   - General safety.

2. Adequate environmental conditions are maintained in the University of Toledo Medical Center Clinical Laboratory.

Clinical Pathologist Review

1. Analytic phase:
   - Blood smear slides are reviewed for correct identification and assessed under the microscope for quality of the smear.
   - Electrophoresis or immunofixation plates are visually reviewed for readability.
   - Reports (blood smears, protein electrophoresis, immunofixation, transfusion) are assessed for correct patient identification, spelling, and diagnostic interpretation.
2. Post-analytic phase:
   - Multiple components are reviewed in the post analytic phase that are imperative to our quality plan.
     - Clinical Hematology: monthly review of 6 or more peripheral blood smear slides and reports
     - Clinical Serology:
       - monthly review of 4 or more immunofixation reports with immunofixation plates
       - monthly review of 6 or more protein electrophoresis reports with electrophoresis plates

    - Clinical Transfusion: monthly review of 4 or more reports
- Documentation:
    - All cases pulled for review are documented. The review documents are scanned and located at the following location: Z DRIVE, PATHOLOGY, COMMON, QA
- Case revisions:
    - Minor discrepancies require no action.
    - Major discrepancies may require a report revision. Major discrepancies are defined as those that may affect patient care. The physical blood smear or plate and the report is reviewed with the diagnostic clinical pathologist. If a report revision is necessary, the corrected report is issued and patients' physician is notified as necessary.
- Trends:
    - Department goals are to keep diagnostic case revision percentages under 5% of total cases.
    - If a clinical pathologist makes repetitive errors, re-education is undertaken.

This monthly Clinical Pathology QA review is reported at the Clinical Pathology Faculty meeting.

(D) References

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Approved by:

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3/11/2025

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Date

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Name
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3/20/2025

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Date

Review/Revision Completed by:
Joshua Otiso, Administrative Director, Laboratory.

Policies Superseded by This Policy:

- *QPCLINLAB2017*

Initial effective date: 10/1994

All Review/Revision Dates:

01/2005	
1/3/2006	
01/03/2007	
01/02/2008	
02/27/2009	
03/01/2013	
03/02/2015	
03/01/2017	
03/01/2019	
03/01/2023	
03/01/2025	

Next review date: 03/2027