QMP0001.3

Quality Control and Quality Assurance Plan
Pathology and Laboratory Medicine Service
VAMHCS

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Reviewed/Revised 6/26/2017

QUALITY MANAGEMENT SYSTEM INDEX

Quality System Essentials:

The Quality Control & Quality Assurance plan is comprised of 12 Quality System Essentials (QSEs) and the Quality Management Plan (i.e. the *monitors* in QSE IX and X). The following 12 sections comprise the Quality System Essentials:

VA Maryland Healthcare System
Pathology and Laboratory Medicine Service

QUALITY MANAGEMENT SYSTEM

I. Purpose and Objectives:

A. The Veterans Administration Maryland Health Care System (VAMHCS) Pathology and Laboratory Medicine Service (P&LMS) maintains a plan to ensure the highest standards of laboratory testing to support the VHA's mission of patient care, education and research; and that meets or exceeds the regulatory requirements of the Food and Drug Administration (FDA) as well as the quality standards of the American Association of Blood Banks (AABB), the College of American Pathologists (CAP), Clinical Laboratory Improvement Amendment of 1988 (CLIA 88) and The Joint Commission (TJC).

II. Policy:

The Pathology and Laboratory Medicine Service (P&LMS) maintains a quality control plan (QCP) to ensure patient testing performed by the laboratory is of high quality from sample procurement through the final result reporting.

III. Scope:

1. The P&LMS Quality Control & Quality Assurance Plan will document the processes used to ensure the highest quality products, services and personnel are developed throughout the laboratory.

2. The scope of operations for VAMHCS Pathology and Laboratory Medicine Service includes the following disciplines:

    1. Anatomic Pathology (Surgical Pathology, Cytopathology, Autopsy)
    2. Ancillary Testing (Point of Care)
    3. General Laboratory (Chemistry, Special Chemistry, Blood Gases, Hematology, Bone Marrow, Coagulation, Urinalysis)
    4. Microbiology (Bacteriology, Mycology, Serology, Molecular Diagnostics)
    5. Phlebotomy
    6. Send-Out Testing (processing, shipping and result reporting for tests not performed on site)
    7. Transfusion Medicine

3. The highest standards are maintained through continuous self-monitoring of each component of the plan, customer feedback and appropriate modifications to the plan, as required.

4. The Elements of the Quality Control & Quality Assurance Plan will be used to:

    1. Ensure that specimen testing is of the highest quality from sample procurement through final result.
    2. Implement effective processes and system controls to ensure the highest possible product quality, service quality and patient safety.
    3. Detect and, most importantly, strive to prevent errors in laboratory practice. This can be achieved by reducing process variations, which can cause errors.
    4. Improve the efficiency of processes without sacrificing quality or safety.
    5. Respond to customer needs for timely, accurate services and products.
    6. Develop and maintain competent staff.
    7. Comply with all applicable regulations and accreditation standards.

5. Assessments used to ensure the reliability of the reported laboratory data may include:

    1. Pre-analytical Controls:
        a. Procurement of the specimen.
        b. Transportation of the specimen.
        c. Accessioning and processing the specimen.
        d. Procurement, storage and inventory of supplies.
        e. Recruitment and retraining of qualified personnel.

    2. Analytical Controls:
        a. Written policies and procedure manuals.
        b. Internal and external quality control.
        c. Instrument function monitors.
        d. Instrument accuracy monitors.
        e. System for correction of instrument malfunction.
        f. System for monitoring verification of reagents and purity of water.
        g. System for evaluating cleanliness and accuracy of glassware.

    3. Post-analytical Controls:
        a. Verification of reports by operators.
        b. Critical value flags in both the computer verification screen and the computer report.
        c. Delta check parameters in the computer verification screen.
        d. Supervisor review of reported data.

Historical Record

DATE (Enter date put into service, revised, reviewed or removed)	WRITTEN/ REVISED BY	STAFF EDUCATION METHOD	SUPERVISOR/ DESIGNEE REVIEW (Lab Manager/QM Tech)
Put into Svc: 9/28/2015 Major re-write of Quality Plan	J. Wade Technical Specialist/Lab Manager	Paper Copy Med Training Share Point	JWade 9/28/15
Revised/ Reviewed 08/18/16- Updated delegated functions.	Karla Peralta, QM MT	Paper Copy Med Training Share Point	JWade 8/18/16
Revised/ Reviewed 06/26/16- Added 2 new position descriptions: Microbiology TS and Cytotechnologist. Updated Process Control section.	Karla Peralta, QM MT	Paper Copy Med Training Share Point Share Drive	JWade 6/26/17

QUALITY SYSTEM ESSENTIALS

A. Organization (Quality Leadership)

All staff is qualified to perform the duties specified below as per CFR Title 42 Part 493-Laboratory Requirements. Our quality leadership is as follows:

1. *The P&LMS Service Chief (Laboratory Director)* The Director is responsible for the following:

   a. Serves as the Responsible Head for P&LMS. Ensures that Department, Facility and Network mission, vision and values are achieved while operating in accordance with VHA and Network policies and standards of federal professional and accrediting agencies external to VHA (to include other federal, state and local authorities).

   b. Oversees all phases of the Laboratory QCP.
      Reviews the QCP on a yearly basis, revises as needed and reports the findings in the Laboratory minutes. Ensures sufficient funding for quality control materials and expendable supplies and their timely delivery.
      Ensures that there are adequate proficiency testing procedures sufficient for the extent of testing performed in the laboratory.
      a) Reviews responses/corrective actions for unsatisfactory PT survey results.

   b) Ensures that lab test results are adequately communicated.
      1) Biennial review of result reports (if designated, must be to someone with Service Chief's qualifications).

   4. Is responsible and accountable for all professional activities within the specialty including research, teaching programs, strategic planning and education oversight appropriate to the needs of the service and the facility.
   5. Ensures participation in performance improvement activities.
   6. Ensures equipment and supplies selected meet the technical, clinical and operational needs of the laboratory (may be designated to supervisor and/or Lab Manager).
   7. Approves:
      1) All new and substantially revised clinical lab and anatomic pathology policies and procedures. *This task may not be designated.*
      2) New method validation criteria (if designated, must be to someone with medical Director's qualifications).
   8. The Laboratory Director will evaluate the pathologists and the performance on non-pathologists who assist in gross tissue examinations on a regular, periodic basis. In conjunction with the Lab Manager, the Laboratory Director will evaluate the supervisors and the Ancillary Testing Coordinator (ATC) based on their regulatory responsibilities.
      1) Monitors and evaluates the professional performance of all pathologists within the Pathology and Laboratory Medicine Service.

2) Delegate responsibility to other staff as needed, with appropriate oversight. (In lieu of separate designee lists, the tasks that the Director has delegated are listed below as responsibilities of that position).

2. *The Division Director/Technical Supervisor of Anatomic Pathology (*to include surgical pathology and histology, autopsy and cytology) He/she is responsible for assisting the Service Chief in developing and monitoring all quality activities in AP and for:
   a. May perform biennial review of AP (surgical pathology, histology, cytology and autopsy) procedures.
   b. Review of unsatisfactory proficiency testing and resultant corrective action as needed in immunohistochemistry.
   c. Review of new method validation criteria in those sections.
   d. Monitors and evaluates the quality and appropriateness of Anatomic and Clinical Pathology Services provided and ensures the provision of other AP services as requested and appropriate.
   e. Conducts Performance and Competency Assessment of subordinate supervisors.
   f. Authority to approve and sign proficiency testing.

3. *The Division director/Technical Supervisor of Hematopathology* (to include bone marrow examination, and clinical hematology testing). He/she is responsible for assisting the Service Chief in developing and monitoring all quality activities in Hematopathology and for:
   a. May perform biennial review of Hematology, Coagulation, Bone Marrow and Urinalysis procedures.
   b. Review of proficiency testing and resultant corrective action as needed in Hematopathology (Hematology, Urinalysis and Coagulation).
   c. Review of new method validation criteria in those sections.
   d. Approves any QC rule over-rides and reviews/evaluates any patient results that were included in an analytically unacceptable test run.
   e. Conducts Performance and Competency Assessment of subordinate supervisors.
   f. Authority to approve and sign proficiency testing.

4. *The Division Director/Technical Supervisor of Chemistry* (to include accessioning, STAT lab and send out testing). He/she is responsible for assisting the Service Chief in developing and monitoring all quality activities in Chemistry and for:
   a. May perform biennial review of procedures.
   b. Review of unsatisfactory proficiency testing and resultant corrective action as needed.
   c. Review of new method validation criteria in those sections.

d. Ensures equipment and supplies selected meet the technical, clinical and operational needs of the laboratory.
e. Approves any QC rule over-rides and reviews/evaluates any patient results that were included in an analytically unacceptable test run.
f. Conducts Performance and Competency Assessment of subordinate supervisors.
g. Review of proficiency testing and resultant corrective action as needed.
h. Authority to approve and sign proficiency testing.

5. *The Division Director/Technical Supervisor of Microbiology and Molecular* Laboratory. He/she is responsible for assisting the Service Chief in developing and monitoring all quality activities in Microbiology, Immunology and Molecular Laboratory for:
   a. Performs biennial review of Microbiology/Molecular Laboratory procedures.
   b. Review of new method validation criteria in those sections.
   c. Ensures equipment and supplies selected meet the technical, clinical and operational needs of the laboratory.
   d. Provides technical and administrative support to the technologists, Microbiologists, and technicians.
   e. Conducts Performance and Competency Assessment of subordinate supervisors.
   f. Has an active role in the Division of Infectious Disease. This includes coordination and active participation in research programs directly related to patient care.
   g. Consults with the medical and surgical staff to ascertain views on their needs with respect to differential diagnosis when an infection or a lesion is suspected.
   h. Active member of the hospital Infections Committee, develops epidemiological studies, analyzes epidemiological data and provides expert advice and guidance.
   i. Authority to approve and sign proficiency testing.

6. *The Division Director/Technical Supervisor of Transfusion Medicine*. Serves as the Administrative Supervisor for Transfusion Service operations and assures compliance with the FDA, CAP/AABB and other accrediting agencies.
   a. Designated to perform biennial review of Transfusion Medicine manuals.
   b. Has the authority to establish or make changes to the blood bank's or transfusion service's quality system. Participates in management review of the blood bank quality system.
   c. Provides general oversight for the Transfusion Service and transfusion practices throughout the facility.
   d. Provides consultation to other clinical providers regarding appropriateness of laboratory tests and transfusion practice.
   e. Provides oversight of the provision of blood components and/or services.

f. Approves all transfusion service policies, processes and procedures, and approves incidents of justified deviations.
g. Ensures equipment and supplies selected meet the technical, clinical and operational needs of the laboratory.
h. Review of new method validation criteria
i. Conducts Performance and Competency Assessment of subordinate supervisors.
j. Authority to approve and sign proficiency testing.

7. *The Clinical Lab Manager (Supervisory Health Systems Specialist)* assists the Service Chief with the implementation and monitoring of all administrative and work processes including:
   a. Human resource functions such as administering disciplinary action and maintaining position descriptions.
   b. Serving as a liaison with employee unions.
   c. Administration of the leave policy
   d. General lab staffing levels, lab budget planning and foresight.
   e. Promotes and supports continuous quality improvement activities by monitoring standards of performance, QC and QI including tests transferred to outside (reference) labs.
   f. Interpretation, correlation and communication of laboratory data.
   g. Assisting the responsible technologist in the development and maintenance of the Quality management System. Reviews and approves the Quality Management System at least annually.
   h. Performs biennial review of Administrative, Clerical, General Lab, Safety and Ancillary Testing policies and procedures.
   i. Personnel selection providing for sufficient and adequate staffing.
   j. Interaction with physicians and/or medical staff, patients, administration, government and other agencies.
   k. Maintaining a safe laboratory environment.
   l. Reviews equipment and supply selection.
   m. Conducts Performance and Competency Assessment of subordinate supervisors
   n. Reviews Laboratory General Standard Operating Procedures and Policies.

5. Each *Section Supervisor* (general) oversees the activities of their respective section. The supervisor must keep the technologists/technicians in their area on task. The supervisor assumes primary responsibility for the following:
   a. Oversight of day-to-day operations (including staffing levels, schedules, workload, equipment, consumables, supplies, budget, physical plant, etc.).
   b. Monthly review of performance specific data including review of quality control and other statistics and follow-up when QC unacceptable.
   c. Oversight of regulatory requirements.

d. Oversight of personnel performing and reporting test results (including input into selection, training, competency assessments, discipline and performance issues).
e. Review of proficiency testing results, self-assessments and on-going monitors.
f. Development, implementation and biennial review of their sections' SOP manuals.
g. Review of quality results and/or monitoring of Reference Labs are designated to the Quality Management Technologist.
h. Interaction and communication with appropriate hospital staff regarding changes in practice, etc.
i. Interaction and communication with the Service Chief.

6. *The Quality Management Medical Technologist* is responsible for:
   a. Serving as a recognized expert and provides authoritative consultative services to management at all levels of the organization.
   b. Creating and applies reengineering and continuous performance improvement initiatives, both within the laboratory and/or the organization.
   c. Maintaining a laboratory performance improvement program and ensures monitoring of components and customer feedback to:
      1) Implement effective processes and system controls to ensure the highest possible product quality, service quality, and patient safety.
      2) Detect and prevent errors in laboratory practice.
      3) Reduce process variations that can cause errors.
      4) Improve efficiency of processes without sacrificing quality or safety.
      5) Comply with all applicable laws, regulations, policies, precedents, and accreditation requirements.
   d. Monitoring and helps maintain laboratory readiness for accreditation by performing regulatory review and internal assessments.
   e. Identifying, defining, and resolving issues associated with complex aspects of the collected data.
   f. Providing authoritative representation and interaction with management officials, test reagent and instrumentation manufacturers, and with organizations involved in inter-laboratory quality assurance and proficiency testing.
   g. Applying concepts of quality design that are consistent with current or future series of standards for quality management.

7. The *Medical Technologist Specialist – Blood Bank* is considered subject expert in their respective section.

8. *Technical Specialist- Microbiology-*

   a. Maintains records and procedure manuals by writing new procedures and/or updating existing procedures as necessary as directed by the supervisor.
   b. Researches qualitative and quantitative methods in the appropriate specialty areas; reviews quality control data and statistical analysis as required for quality assurance monitors.
   c. Acts as the primary trainer for new staff and is responsible for coordination of training in the methods and techniques of the Microbiology laboratory.
   d. Independently recognizes discrepancies in media, reagents, test procedures, unusual organisms/results and recommends reflex testing.
   e. Reviews the incomplete status report daily for accuracy and completeness.
   f. Is responsible as primary source of information for maintaining current and future instrumentation and automation and performs validation/method verification studies for new systems.

8. *Ancillary Testing Coordinator (ATC)*
   a. Oversight of the Ancillary Testing Program (a direct patient care operation) including reviewing flagged patient test results, equipment, consumables, supplies, budget, physical plant, etc.
   b. Development, implementation and maintenance of the section's procedures, policies and Center Memoranda.
   c. Interaction and communication with appropriate hospital staff regarding changes in practice, etc.
   d. Acts as technical oversight supervisor for quality control, records control, proficiency testing, quality monitors and inspection and accreditation for all ancillary testing sites.
   e. Participates in the selection of methodologies appropriate for clinical use of the test, the validation of methods and test procedures performed and the establishment of the test performance characteristics, including precision and accuracy.
   f. Performs and documents training of Baltimore, Perry Point and CBOCs super-users and co-signs completed annual competency evaluation for all persons who perform ancillary testing.
   g. Ensures enrollment and participation in a proficiency program commensurate with the testing services offered and oversees necessary remedial action when necessary.
   h. The Ancillary Testing Coordinator will report non-compliance and performance issues to the Service Chief P&LMS, the Lab manager and the on-site Supervisor.

9. *Medical Technologist / Medical Laboratory Technician*
   a. Responsible for immediate review of all QC results and appropriate follow-up action prior to the release of patient results.

b. A technologist may additionally write SOPs, perform high complexity testing and consult with providers.
c. Both can be designated to organize and maintain a training program for MT/MLT student rotations under the direction of the section supervisor and/or actively work on the bench with the students.
d. Both can assist with training of staff new to the section.

10. Cytotechnologist

a. Reads all medical and gynecological material submitted for cytology from the following VAMHCS facilities: Baltimore, Perry Point and all CBOCs.
b. Responsible for reading and providing diagnostic evaluation on all pap smears.
c. Supply test kits to the gynecology clinics within the above mentioned facilities and work in conjunction with the clinicians to train all users.
d. Responsible for training all hospital services to the proper fixation and technique to use for thin prep processing.
e. Monitors the processing and quality of preparations to insure optimum slides for diagnostic interpretation.
f. Maintains familiarity with current literature in Anatomic Pathology as it regards to processing and diagnostic evaluation.
g. Participates in continuing education and cytopathology conference with staff pathologists to review and discuss inconclusive sign outs.
h. Assist resident in orientation to VA methodology.
i. Responsible for adequate inventory of supplies and equipment.
j. Responsible for release of slides and blocks from this hospital to other medical and treating facilities.

11. *Cytology Technician*

a. Prepares cytological specimens for microscopy analysis.
b. Accession, process and stain routine gynecological slides. Process non-gynecological specimens and evaluate requested procedures to determine the suitability of the specimen.
c. Order and maintain supplies for Cytology Lab.
d. Perform daily/monthly QA/QC in Cytology Lab.
e. Prepare GYN specimens for send out for HPV testing.
f. Prepare and mail cytology and histology slides and blocks for send out, as needed.

12. *Histopathology Technician*

a. Accession surgical specimens.
b. Specimen preparation (embedding, cutting tissue, H&E staining, checking stain quality daily).
c. Perform highly complex special stains.
d. Assist pathologist with intra-operative frozen sections.
e. Grossing assistance to the surgical pathology residents.
f. Prepare bone specimen and bone marrow specimens for diagnostic interpretation.

g. Maintenance of Histology equipment.
h. Ensure adequate stock.

13. *Laboratory Information Manager (LIM or ADPAC)* is the computer support person responsible for:
    a. Liaison between lab, IT and the VISN 5 network.
    b. Instrument interface manager, including monitoring the fidelity and integrity of data transmission.
    c. Biennial review of LIS procedure manual.
    d. Lab hardware/software manager including troubleshooting and responding to downtime.

14. Safety Officer
    a. Oversees Lab Safety program (including development and maintenance of procedures, training, regulatory compliance and tracking and tending of safety issues).
    b. Liaison with hospital safety committee.
    c. Responds to and documents safety alerts and recalls.

15. *Budget and Fiscal Clerk*
    a. Ensures that staff has the appropriate resources available to perform their duties.
    b. Is the lab liaison with vendors and maintains copies of contracts, etc.
    c. Coordinates ordering, storage and organization of supplies.
    d. Is responsible for following-up on back orders.
    e. Oversees the budget grid, credit card orders and GIP related issues.
    f. Is designated as timekeeper for the Path and Lab Service.

16. *Secretary (OA)*
    a. Receives and screens visitors and telephone calls.
    b. Transcribes anatomic pathology reports, as well as other recurring and one-of-a-kind detailed reports and documents.
    c. Is designated as timekeeper for the Path and Lab Service.
    d. Serves as TMS coordinator.
    e. Maintains office files.

APPLICABLE DOCUMENTS AND PROCEDURES: **I. Organization**

- Current organization Charts
- VISN 5 Mission, Vision & Values VAMHCS INTRANET
- Prevention of Workplace Harassment VAMHCS 512-00E-004
- Integrated Ethics VAMHCS 512-00-109
- Employee Responsibilities & Conduct VAMHCS 512-05HR-010

B. Personnel (Human Resources)

P&LMS employs individuals qualified by education and experience who are provided with adequate training to perform all assigned tasks and who are assessed periodically for on-going competence.

1. Personnel Selection

   a. There are appropriate and defined qualifications for each job type.

   b. Job descriptions or functional statements are written and maintained for each position. Candidates must meet the qualifications defined in the job description, as described in applicable regulations.

   c. Candidates must provide documentation of education, training, certification as required and experience relevant to the position for which they are being considered.

2. Orientation and training of New Employees

   i. New employees are provided orientation to the facility, to the laboratory service and to the specific section in which they will be assigned.

   ii. General training is provided in the areas of safety, infection control, quality management, information security and technology and personnel-related issues.

   iii. Job-specific training based on type and complexity is provided in the performance of all assigned duties. Training / education is mandated prior to beginning or changing a process or procedure.

   iv. Training is considered complete when the employee demonstrates sufficient knowledge and skill to successfully perform all assigned tasks, and initial competency assessment has been successfully completed.

   v. Job-Specific training is documented in a standardized format, (see sample training guideline and checklist in P&LMS SOP) and the documentation is maintained in P&LMS files.

   vi. Retraining is initiated when a need is identified through periodic competency assessment or other performance indicators.

   vii. Records of immunizations, exposures, treatments, visual color discrimination or lack thereof, or other health matters are kept in Employee Health.

viii. Records of employee signature, initials and identification codes are maintained for all employees authorized to perform or review critical processing steps in the transfusion service.

3. Physician privileging occurs every two years. Evaluation of a staff pathologist's performance is done by the Laboratory Medical Director based on data from the Ongoing Physician Practice Evaluation (OPPE).

4. Competency Assessment

   a. Competency assessment is designed to look at all phases of the employee's assigned tasks including problem-solving skills. The process is accomplished in a variety of ways, including but not limited to direct observation, written assessment, review of records and results, and/or the use of internal/external proficiency testing samples.

   b. Competency of each person to perform his/her assigned duties is assessed as below:

      1) Following training and before the person performs patient testing.
      2) During an individual's first year of duties, competency is assessed semiannually.
      3) After an individual has performed his/her duties for a year, competency is assessed annually.

   c. Documentation of competency is recorded and maintained in the P&LMS files.

   d. Supervisory review of valid customer complaints, error/accident reports and/or unsatisfactory performance during competency assessment will initiate retraining and/or reassessment of competency as appropriate.

   e. Competency for specific other skills necessary to perform one's job (such as use of e-mail, VISTA, CPRS, safety, EEO and ADR training, and infection control) will be assessed.

   f. Core competencies of the High Performance Development Model (HPDM) which include such things as technical skills, interpersonal effectiveness, personal mastery and customer service are defined, evaluated and documented.

5. Performance Appraisal

   a. Performance Appraisal Standards are based on job accountability, pre-defined performance standards and performance on competency assessment tasks. The Performance Appraisal Standards include the critical elements of lab procedures, customer service and professional environment.

b. Documentation is recorded in a standardized format and maintained in the employee's official personnel folder.

6. Continuing education and Staff Development

   a. Continuing education is encouraged and, to the extent possible, made available to all employees.

   b. Staff development is provided to meet the changing needs of the laboratory, regulatory and accreditation requirements and, where possible, individual interests and career goals.

   c. Documentation of these activities is maintained.

   d. Trainer Qualification – Selected individuals who meet predetermined qualifications, based on education and/or experience related to specific tasks, may function as trainers.

7. End of Service – The Lab Manager will use the Employee Exit Checklist found as form VA3245 (BT) or VA3245 (PP).

APPLICABLE DOCUMENTS AND PROCEDURES: **II Personnel**

- Clearance Procedure for Separating Employees VAMHCS 512-05HR-032
- Compliance and Business Integrity Program VAMHCS 512-00-017
- Employee Competence VAMHCS 512-05HR-005
- The Talent Management System (TMS) VAMHCS 512-14/E&AA-015
- Performance Appraisal Program VAMHCS 512-05HR-015
- "Laboratory Chemical Hygiene Plan" VAMHCS SOP 113/PL-008
- "Laboratory Safety Plan" VAMHCS SOP 113/PL-006
- P&LMS SOP: Selection, Training, Competency Assessment and Education of P&LMS Personnel (GEN00029).
  - Personnel folders are kept in the laboratory administration office and electronic copies are kept accessible to the lab director.

C. Equipment

1. Selection

   a. The section supervisor will determine the equipment specifications and functionality required based on patient care needs.

   b. New equipment shall be approved by the Lab Manager and by the Director P&LMS.

   c. Under the provisions of VAMHCS Policy Memorandum 512-90-100 new equipment may be tested, evaluated or demonstrated to aid in the selection process.

2. Acquisition – See QSE IV – Purchasing and Inventory for details on appropriate procurement sources and facility Logistics responsibilities. Contracting Officers of Logistics and Purchase Card Holders have been delegated procurement authority to enter into agreements or contractual commitments to prospective contractors and, as such, are the personnel with authority to make purchases for the VAMHCS.

3. Equipment Qualification

   a. P&LMS assures that each new piece of equipment is properly installed (installation qualification) by qualified personnel, meets expected performance standards (operational qualification) and maintains a program of calibration, preventive maintenance, validation and quality control appropriate for each type of equipment to verify that its performance (performance qualification) is suitable for the intended application.

   b. Refer to individual SOPs for detailed instructions, maintenance logs and records. All equipment is assessed prior to being placed into service, during use at defined intervals and after major repairs.

4. Identification – each piece of equipment will be uniquely identified.

5. Validation

   a. All new pieces of equipment will be tested to document that the equipment meets the manufacturers published performance standards.

   b. Review and/or establishment of method performance specifications will include accuracy, precision, analytic sensitivity, interferences and reportable range (i.e. analytic measurement range (AMR) as applicable.

c. After repairs, an abbreviated validation must be performed prior to resuming patient testing.
d. Method performance specifications will be retained while the method is in use and for at least 2 years after its discontinuation (10 years after for Blood Bank)

6. Calibration

   a. Calibration will be performed periodically on all measuring devices as defined in individual procedures.

   b. Calibration is performed according to procedures defined by the manufacturer, regulations, requirements and accreditation standards. Ata minimum, recalibration or calibration/verification will occur:

      1) At changes of reagent lots unless the laboratory can demonstrate that the use of different lots does not affect the accuracy or the range of patient test data.
      2) When QC fails to meet established criteria.
      3) After major preventive maintenance or a change of a critical instrument component.
      4) At least every 6 months.

   c. Calibration documentation is maintained, including equipment identification, dates, calibration results and actions taken/equipment disposition.

7. Validation of existing methods will include, as applicable:

   a. Method Comparison: If the laboratory uses more than one instrument/method to test for a given analyte, the instruments/methods are checked against each other at least twice a year for correlation of results.
   b. Reference Range Verification.
   c. Calibration.
   d. Linearity of the AMR.
   e. Interferences.

8. Preventive Maintenance

   a. Lab equipment will have periodic inspections or preventive maintenance (PM) if necessary based on documented standards at intervals not to exceed one year.

   b. Preventive maintenance is performed as defined in individual SOPs, on each type of equipment based on the manufacturer's recommendations, regulatory requirements, accreditation standards and internal requirements.

c. Preventive maintenance documentation is maintained, including equipment identification, dates, preventive maintenance results and actions taken/equipment disposition.

d. BioMed will maintain service records of in house equipment PM.

9. Service and Repair

a. Repairs are performed by the technical staff, the Clinical Engineering section of the VAMHCS and/or the manufacturer.

b. Requests for repair of equipment through the Clinical Engineering section will be made through an Electronic Engineering Work Order in Vista. Engineering will then initiate and approve the request for any repairs and contract outside sources as necessary.

c. Safe Medical Device Reporting – all staff is trained in the process of tagging out and reporting unsafe equipment. Management communicates all manufacturer recalls and notices to end-users and ensures unsafe equipment or supplies are taken out of service.

10. Files and Records

a. For equipment not serviced in house by BioMed, the official equipment preventive maintenance and service/repair history will be maintained in the laboratory, accessible to instrument users.

11. Reagents

a. Reagents, calibrators, cellular controls and solutions are properly labeled, as applicable and appropriate (a traceable log sheet is acceptable), with the following:
   1) Content and quantity, concentration or titer
   2) Storage requirements
   3) Date prepared or reconstituted by lab
   4) Expiration date (note: a new expiration date must be recorded if opening the container changes the expiration date and/or storage requirement)

b. All reagents and media are stored as recommended by the manufacturer.

c. All reagents and media are used within their indicated expiration date.

d. New reagent lots and/or shipments are checked against old reagent lots or with suitable reference material before or concurrently with being placed into service.

e. If there are multiple components of a reagent kit, the lab uses components of the reagent kits only within the kit lot unless otherwise specified by the manufacturer.

APPLICABLE DOCUMENTS AND PROCEDURES: **III. Equipment**

- Testing and Demonstration of Supplies and Equipment, VAMHCS Policy Memorandum 512-90-12
- Equipment Assessment Program, VAMHCS Policy Memorandum 512-90-100
- P&LMS SOP, New Method Validation Procedure
  - Documentation of instrument/method validation is found in the applicable sections.

D. Purchasing and Inventory (Supplier Issues)

Currently P&LMS utilizes GIP (Generic Inventory Package), an effective inventory management system that is a prerequisite to an efficiently functioning laboratory. An efficient Ordering Process, Inventory Review Process, and Inventory Receipt/Restocking Process ensure that:

1) Patient care will not be interrupted.
2) Financial credibility of the hospital is maintained with vendors.
3) Reporting of lab data is not delayed.
4) Morale of the laboratory staff is maintained.

1. Supply Inventory System (Ordering Process)

   a. The GIP technician will maintain a one month on hand level of stock at any given time.

   b. He/she will scan the barcodes to generate an "autogen" request for all supplies with less than a one month level on hand.

   c. The GIP tech will coordinate with each section supervisor to establish the required stock levels and which items will be part of the GIP package.

   d. The GIP tech has full responsibility for maintaining room 4D 135 as a primary storage area at Baltimore and room 1B-110 at Perry Point.

   e. Items not covered by GIP will be ordered on as needed basis by either a 2237 for orders greater than $3000.00 (including yearly Purchase Orders (PO) and Cost per test agreements) or by credit card for orders less than $3000.00.

   f. Adjustments to yearly contracts/Purchase Orders (PO) to decrease/increase the volume by:
      1) Directing a memo to Chief, A&MMS to add or delete to yearly order.
      2) Submitting the change to Chief, P&LMS for signature.
      3) Requires knowledge of:
         a) Current inventory (minimum of monthly review).
         b) Undelivered orders status (minimum weekly review after due date).
         c) Quarterly standing orders and delivery dates.
         d) Minimum ordering quantities.
         e) Minimum lead time required to process an order.
         f) Minimum lead time for delivery.
         g) Expiration dates of perishable items-by lot number.
         h) Available storage space for perishable & non-perishable items.
         i) Vendor pricing.
         j) Alternate sources of supplies.
         k) GIP (Generic Inventory Package).

2. Inventory Review Process

   a. At least weekly, the GIP tech will review the current levels of supplies and auto-generate the necessary 2237's to ensure a level of supplies to last 30 days. Section Supervisor or their designee will review the monthly QC material, reagents, calibrators and expendable supply inventory for possible shortages with the GIP tech.

   b. At least weekly, the Section Supervisor or their designee and the GIP tech will review the status of all undelivered orders and follow-up on their expected delivery.

   c. Prior to the last day of each month the Section Supervisor or their designee will review the inventory for their section and adjust GIP accordingly with assistance from GIP Inventory Specialist.

3. Inventory Problems

   a. The Supervisory Health System Specialist will be promptly informed to seek resolution to inventory problems.

   b. Present a copy of the order with purchase order number.

   c. Notify Health System Specialist of problem resolution upon receipt of supplies.

4. Contracts

   a. Contracts are reviewed in accordance with the Federal Procurement Regulations Act. The approved list of vendors is based upon evaluation of their qualifications and performance.

   b. Contracts are maintained with Reference Labs for testing not performed on site.

APPLICABLE DOCUMENTS AND PROCEDURES: **IV. Purchasing and Inventory**

- Clinical Product Review Committee, VAMHCS Policy Memorandum 512-90-102

E. Process Control

The laboratory will identify the work processes in its operations and each lab section will start documenting them through flowcharting as well as detailed standard operating procedures (SOPs).

- The ultimate goal of process control is to standardize and control processes in order to produce predictable output.
- Processes must be validated to ensure they perform as expected, controlled to prevent errors and monitored to detect errors.
- SOPs, system checks, quality control, process specifications and acceptability ranges must be defined and in place for each process.
- Methods of process control ensure that process steps are accomplished and performed in a manner consistent with defined procedures.
- Deviations are documented as they occur or when they are discovered, with corrective action implemented recorded and evaluated for effectiveness.
- Periodic self-assessments and external regulatory inspections help to gauge the effectiveness of process control.

1. **Pre-Analytic**
   a. Test ordering and specimen collection information is uniformly available to all staff via VISTA/CPRS, the computerized patient record system. (See Information Management Section). Details regarding patient prep, requisitions, specimen collection containers, volume, labeling, transport and time constraints are defined. P&LMS adheres to and monitors Medical Center policies regarding phlebotomy, patient identification and specimen labeling.

   b. Specimens and/or requisitions are assessed for acceptability before testing.

   c. There is a system in place to identify all specimens (including aliquots and those from outside sources).

   d. Packing/shipping requirements are defined. Samples are handled, stored, distributed and transported in a manner that ensures traceability, prevents damage and deterioration to within acceptable levels.

2. **Analytic**

   a. Process Validation: P&LMS validates its critical processes (both technical and administrative), procedures and equipment to assure that they are efficient and consistently produce a quality product or service, meeting pre-defined standards. There is a mechanism to verify comparability of results from instrument to instrument, method to method and site to site.

      1) The facility uses a consistent approach to validation and documentation of the validation process.

2) Validation verification is performed on all new processes or procedures.
3) New or changed products/services are controlled and shown to be effective prior to being put into service.

b. System checks monitor each important step in a process. Some are built into SOPs and are documented as part of the process. They are real time monitors. For example: daily QC, clerical checks, instrument calibration, blood utilization, reviews and recording of specific operating conditions such as temperatures, dates and initials of staff performing process.

i. Quality control material-The laboratory follows, at a minimum, the manufacturer quality control instructions and CLIA/CAP requirements and for waived tests and non-waived tests. The laboratory runs positive and negative controls for *qualitative* tests each day of patient testing and at least 2 levels of quality control material (1 normal and 1 abnormal) for *quantitative* tests each day of patient testing.

ii. Coagulation test require 2 levels every 8 hours of patient testing and Blood Gas requires 1 level every 8 hours each day of patient testing. For tests where an Individualized Quality Control Plan (IQCP) is implemented, a developed and director approved IQCP plan supersedes these instructions.

iii. The Quality Control Plan (QCP) must comply with regulatory and CAP accreditation requirements and follow at least minimum manufacturer requirements. The QCP will be monitored monthly by the section supervisor or designee. The plan will be reviewed and reapproved annually by the director or designee.

iv. The technologist/technician performing the test will review daily QC data. On at least a weekly basis, supervisor or designee will review QC data for shifts or trends. The Section Supervisor will review all QC data monthly.

v. Unacceptable control results- When results obtained for controls are outside the acceptable range, the technologist/technician performing the studies will troubleshoot the unacceptable values. The following criteria are the minimal requirements for accepting or rejecting QC data:

a. Quantitative Tests: If all control material results fall within two standard deviations (SD) from the established means for each level, the system is operable and patient data may be reported.
b. If more than one level of control material has results falling outside "2SD", the system is inoperable, patient data cannot be reported, and corrective action must be initiated.
c. Determine if the previous value for the same level of control and material has exceeded 2SD's in either direction. If that is the case, the run should be rejected, and corrective action initiated. If not, proceed to next step.

vi. Semi-quantitative and qualitative assays:

a. If established limits are exceeded for any semi-quantitative assay, the system is considered out of control, and corrective action must be initiated.
b. In qualitative testing, if a negative control yields a positive value or a positive control yields a negative value, the system is considered out of control and corrective action must be initiated.

vii. Corrective Actions:

a. Inform supervisor of the problem. If testing is going to be delayed the Laboratory Director or designee should be notified.
b. Re-assay the control material in question. If this run is within 2SD of the mean, the system is operable. If not proceed to the next step.
c. Reconstitute (if applicable) or open a fresh vial of control material and re-assay. If the failed value is now within 2SD of the mean, the system is operable. If not, proceed to the next step.
d. Replace reagents for the analyte in question and re-assay control material. If a value within 2SD of the mean is obtained, the system is operable. If not, proceed to the next step.
e. Some analytes may require recalibration. Although it is not necessarily true for all assays. If recalibrating, make sure to use freshly made reference material and re-assay control material. If a value within 2SD of the mean is obtained, the system is operable. If not, proceed to the next step.
f. Verify instrument function as detailed in the operator's manual. Re-assay control material. If a value within 2SD of the mean is obtained, the system is operable. If not, proceed to the next step.
g. Call the vendor. The technical representative might want to troubleshoot over the phone before sending out an engineer for service.
h. While waiting for service to arrive, leave a notification note that service is on the way also note the reference number for the call. Start-up the backup analyzer.

c. SOP manuals provide standardization and minimize variation and error in P&LMS. Each section develops and maintains comprehensive standard operating procedure (SOP) manuals covering all critical functions (technical, clerical and administrative) performed by the service. All processes and procedures are followed. See also Documents and Records section.

d. Quality Control is performed on reagents, equipment and blood products and ensures that everything functions as expected. Quality control will be established,

validated performed and reviewed as per CLSI and section specific CAP guidelines. There is documentation of monthly evaluation of instrument maintenance and function, including temperatures of refrigerators/freezers in which reagents or patient specimens are kept. Individual SOPs define this review (when and by whom), tolerance limits and corrective action to use when limits are exceeded.

1) All reagents used by P&LMS meet or exceed FDA and CAP requirements. Quality control testing on reagents is performed each day of use, per manufacturer's recommendation, and SOP. Documentation is maintained of all testing performed.
2) All equipment in use meets or exceeds FDA, AABB and CAP requirements.
3) Blood component Quality Control meets or exceeds the standards of the FDA, CAP and AABB. All blood products modified at this facility are included in the program.

e. The Transfusion Service maintains a label control system which:

1) Assures that all labels meet all applicable regulatory and accreditation requirements.
2) Defines a process for receipt, inspection and testing of each batch of labels before use.
3) Maintains a master log of labels in current use.

f. Water supply/glassware standards are defined and monitored.

g. Equipment: There is documentation of monthly evaluation of instrument maintenance and function, including temperatures of refrigerator/freezers in which reagents or patient specimens are kept.

1) Individual SOPs define review of records (when and by whom), tolerance limits and corrective action to use when limits are exceeded.
2) Calibration checks are performed to verify specified operating conditions (e.g., refrigeration, centrifuge, pipette and thermometer checks).

h. Miscellaneous: This facility uses additional mechanisms, as appropriate to the specific task, to provide on-going assurance that procedures are consistently producing the expected results. These include:

1) Employee competencies
2) A means to identify individuals performing each critical step in a process.
3) A means to assure all critical materials, blood components, laboratory samples and patient records are identified and traceable.

4) Process and product specifications are determined from regulations, accreditation standards and customers' needs assessments and are incorporated into their respective procedures.

3. **Post-Analytic**

   a. Testing is reviewed by the technical staff prior to release of results to health care providers. Review and verification requirements are defined in the applicable SOP.

   b. The laboratory must provide useful clinical data. Data must be legible, accurate, reported in clearly designated units of measurement, with applicable reference/therapeutic ranges, and reported to persons authorized by law to receive and use medical information (unless reflexed by the laboratory per policy).

   c. Critical values and turnaround times (TAT) are specified for each test as applicable. Providers are notified of delays and/or critical values. Critical calls are subject to "read-back" requirements as defined by TJCs National Patient Safety goals.

4. **Special Considerations for Blood and Blood Components**

   a. Records of testing, preparation and acceptability are reviewed prior to release of blood or blood components and are defined in the applicable SOP.

   b. Storage requirements for all products, during all phases of production are defined.

   c. Packing/shipping requirements are defined to ensure that blood and products are handled, stored, distributed and transported in a manner that ensures traceability, prevents damage and limits deterioration.

   d. The means to identify and handle non-conforming blood and blood components are incorporated into their respective procedures.

APPLICABLE DOCUMENTS AND PROCEDURES: **E. Process Control**

- Pre
  - Please refer to "Guide to Pathology & Laboratory Medicine Services" Binder
    - Phlebotomy Service
    - Vacutainer Selection
    - VistA Computer-Based "Test Description Information"
    - Methods of Requesting Clinical Laboratory Tests
    - Availability of Clinical Laboratory Tests (STAT's, routine tests, etc.)

- Specimen Labeling
  -Laboratory Specimen Labeling Policy VAMHCS 512-113PL-009
- Delivery of Clinical Laboratory Specimens
- Specimen Rejection by the Laboratory
- Blood Bank
- Collection and Submission of Surgical Pathology Specimens

➢ P&LMS SOP: Packaging and Shipping of Specimens for Analysis (Gen00030)
➢ Procurement, processing, and administration of blood and blood components VAMHCS 512-113/PL-005
➢ Pneumatic Tube System VAMHCS 512-113PL-008
➢ Electronic Incident Reporting Program " Patient Safety/Risk Management Program" VAMHCS 512-00/PS-006
➢ Reporting Incident and Safety concerns (Gen 00010)
  - Occurrence Reporting and Management- Blood Bank Doc.#bbb01013
➢ Specimen Handling and Labeling Policy (OR) VAMHCS 512-112/SC-011

❖ Analytic
➢ Quality Control Program:
  - Blood Bank-Daily Quality Control Document# bbb01005
  - Chemistry- Quality Control Plan, Procedure Manual 1.22 Need electronic copy
  - Hematology- Hematology Quality Assurance and Quality control Hematology Procedure #HE 04 version 1.1
  - Microbiology- Microbiology/Serology/Molecular Quality Management Plan, Procedure #1 version 2.0
  - Point of Care- Ancillary Testing QA BAT 00001

➢ P&LMS SOP: Water Policy (Gen00015)
➢ P&LMS SOP: CAP Compliance and Proficiency Testing Challenges (Gen 00005)
➢ Method Validation-P&LMS SOP, New Method Validation Procedure Documentation of instrument/method validation is found in the applicable sections.
➢ P&LMS SOP: Equipment Maintenance (microscopes, pipettes, centrifuges, hoods, etc.) (Gen00027)
  Attachment A. Chemistry Procedure Manual "Precision Accuracy of Pipettes" Procedure 1.12
➢ P&LMS SOP: Temperature Monitoring (Gen00031)
  - Attachment A. Chemistry Procedure Manual "Thermometer Standards and Calibration" Procedure 1.11
➢ P&LMS SOP: Proficiency Testing Policy- CAP Compliance and Proficiency Testing Challenges Gen05002

❖ Post
➢ Communicating Critical Results/Values VAMHCS 512-00/PS-007

- Availability of Clinical Laboratory Results – Refer to "Guide to Pathology & Laboratory Medicine Services" Page 13
- Availability of Anatomic Pathology Reports- Refer to "Guide to Pathology & Laboratory Medicine Services" Page 16
- P&LMS SOP: STAT Test Results Availability, Critical Values and Turnaround Time (Gen 00013)
- Medical Device Problems/Product Alerts and Recall Policy VAMHCS 512-00/PS-014
- P&LMS SOP: Verbal Lab Test Request Policy (Gen00009)
- P&LMS SOP: Laboratory Communication Policy (Gen 20001)
- P&LMS SOP: Retention of records (Gen 00014)

F. **Information Management** (Computer Systems)

This facility uses a computer system designed to provide additional control over its critical processes. The computer system (hardware and software) is validated and appropriately maintained to assure that it functions according to predetermined specifications. This system helps ensure that all samples/patients, blood and blood components are identified and traceable. It covers all phases of testing – pre-analytic, analytic and post-analytic.

1. Validation:

    a. P&LMS works in conjunction with the Information Computer Systems staff and the VA software developers in the development and implementation of appropriate hardware and software validation protocols. All validation protocols follow FDA and VA regulations/guidelines.

        1) The Vista Blood Establishment Computer Software for transfusion service (VBECS) is considered a Medical Device and has been approved for use by the FDA.

            a) All new hardware in the Transfusion Service is validated at the time of installation and after any significant modification.
            b) All new versions of software and changes ("patches") to the PLMS package are assessed for impact on the Blood Bank software.

    b. All new versions of software and changes ("patches") to the PLMS/Vista package are validated prior to implementation and determined to perform as specified.

    c. Before implementation of software changes, the staff is notified and educated.

2. Release of Information from patient chart is controlled and documented.

3. The Laboratory Computer manual further defines the following processes:

    a. A backup system for computer downtime is defined at both the facility level and in P&LMS.

    b. The VA is committed to privacy and confidentiality of all patient information and is in compliance with applicable regulations. Patient confidentiality is observed in the strictest sense. Staff access to patient records is given solely on a need-to-know basis and is carefully monitored.

    c. Data access security – Security and authorization guidelines for access and use of computer systems by P&LMS staff.

APPLICABLE DOCUMENTS AND PROCEDURES: **F. Information Management**

- Information Security Program VAMHCS 512-ISO-001
- Medical Records VAMHCS 512-136/MAS-003
- Release of Protected Health Information VAMHCS 512-136/MAS-004
- Automated Date Processing (ADP) Contingency Plan- SOP No.113/PL-010
- P&LMS SOP: Retention of records (Gen 00014)

G. **Documents and Records** (Document Control)

1. All Laboratory and Anatomic Pathology records, slides and blocks will be available (at local and remote storage sites) even if the VAMHCS P&LMS should cease to exist.

   a. Discontinuation or merger of Anatomical pathology services at a VA facility are discontinued or merged with another VA maintained per applicable VHA, CAP and Joint commission standards will be transferred to the VA facility where the scope of services for the patients of that facility has been transferred.

   b. Discontinuation or merger of Clinical Laboratory Services (non-Anatomical Pathology) – When clinical laboratory services are discontinued or merged with another VA facility, laboratory management and VA facility quality management will ensure that all records and specimens are maintained per applicable VHA, CAP, AABB, FDA and Joint Commission standards.

2. Document Control

   The facility maintains a system of document control, which includes the following:

   a. Requirement for uniform format for all policies and SOPs.
   b. Storage of documents and records in a manner that maintains integrity prevents unauthorized access and facilitates retrieval.
   c. Defined process for creation, approval and issue of policies/procedures/forms.
   d. Defined process for revisions, changes or modifications to approved policies/procedures/forms.
   e. System for archiving, retention and retrieval of inactive policies, procedures and forms.
   f. Forms are designed to effectively capture outcomes.
   g. Master lists (indexes) of SOPs, policies procedures and forms are maintained by each section.

3. Record Retention

   The facility maintains a system for generation, retention, storage and retrieval of all records related to PLMS, which specifies the following:

   a. Records must be completed according to instructions in the relevant SOP Appendix A.
   b. Records must be retained for the required period as defined by the most stringent requirements of the VA, FDA, AABB, TJC and CAP.
   c. Records must be stored in a manner that maintains their integrity and confidentiality.

d. Records must be stored in a manner that permits their retrieval within a reasonable time frame.

4. Record Review

   a. Records are reviewed in a manner and on a schedule, which meets the most stringent requirements of the VA, FDA, TJC and CAP. Each procedure, as applicable, specifies how and when the review will be done.
   b. There is a process for making changes to reports, records or verified results.

5. Standard Operating Procedures (SOPs)

   a. The laboratory uses a standardized approach to the development and writing of SOPs.
   b. The SOP manuals are maintained and current in order to reflect the actual practices in the facility.
   c. Operator's manuals, manufacturer's package inserts or textbook procedures are never used in place of the written procedure unless included in the body of the manual. They are available in the lab to serve as reference materials.
   d. SOP manuals (electronic and/or printed) are readily available to all staff in each section.
   e. The Medical Lab Director must approve all new policies and procedures as well as any revisions/changes or deviations to SOP. Justification for such deviations must be documented.
   f. As SOPs are updated or removed from service, the original is filed as a "Discontinued SOP" and maintained for the appropriate period of time.
   g. There is a process to control changes to procedures.
   h. All and procedures are reviewed biennially. Policies and memorandums are reviewed triennially. Reference materials, flow charts and quick guides posted at work stations are "controlled" by attaching them to an SOP.
   i. Once approved, all new and revised SOPs are reviewed by staff. Supervisors may use a read and sing page and/or Med Training Program to track review.

APPLICABLE DOCUMENTS AND PROCEDURES: **G. Documents and Records**

- P&LMS SOP: Document Control Policy (Gen00001)
- P&LMS SOP: Retention of Records (Gen14001)
  - VA P&LM National Enforcement Retention Guidelines for Pathology and Laboratory Medicine

H. Occurrence Management (Deviations, Non-conformances and Complications)

Pathology and Laboratory Medicine, in conjunction with the Medical Center Patient Safety/Risk Management Service, employ methods that investigate, detect, assess, correct and prevent errors. P&LMS maintains a system designed to detect and analyze all deviations, failures to meet specified requirements, incidents, accidents and errors that have the potential to impact on the quality or safety of products or services provided. The goal is continuous quality improvement. This process ensures the capture, assessment, investigation and monitoring of events that deviate from SOP or, fail to meet specifications or regulations. This includes the following elements:

1. Monitoring of activities within the laboratory as well as activities that take place elsewhere within the facility, such as specimen collection and transfusion related issues.

2. A defined process for detection, reporting and evaluation of each biological product deviation or suspected transfusion related complication which assures the following:

    a. Notification of FDA of transfusion-related fatalities within required time limits.
    b. Notification of FDA and Regional Commissioners Office (who forwards to national Headquarters) of Biological Product Deviations.
    c. Notification of the blood supplier of adverse recipient reactions linked to the safety, purity and potency of blood products (ex. TRALI, PTTD and bacterial contamination).
    d. Patient/recipient follow-up to rule out adverse effects, when appropriate.
    e. Notification of the transfusion service and clinical team of immediate and delayed transfusion reactions/complications.
    f. A defined process for notification of the Transfusion Service of cases of suspected transfusion-transmitted disease and a standard method of reporting this to the blood supplier.
    g. A defined process for handling transfusion-related "look-backs" as required by the VA, CAP, AABB and FDA regulations.

3. A defined process for prompt documentation, review, follow-up and classification of the deviation/incident/accident/error.

4. P&LMS adheres to the facility's Risk Management department's procedures for reporting Opportunities for Improvement, Close Calls, Patient Incident Reports and Sentinel Events.

5. A defined process for reporting medical device adverse events to the FDA.

6. A defined process to comply with VHA Directive 2009-035 which deals with documentation and reporting of mislabeled, unlabeled, partially labeled, incompletely labeled and illegibly labeled specimens.

7. A defined process to document safety, supply and product/equipment recall issues.

8. A defined process for quarterly environmental testing for Legionella per VHA Directive.

9. Complaints from providers, patients, patient advocate, etc. are documented with other lab errors and occurrences and are addressed on a case-by-case basis.

APPLICABLE DOCUMENTS AND PROCEDURES: **H. Occurrence Management**

- Medical Device Problems/Product Alerts and Recall Policy and Procedure 512-00/PS-014
- Sentinel Event/Root Cause Analysis 512-00/PS-0023
- Electronic Incident Reporting Program 512-00/PS-006
- VHA Directive 1601 A-1 Prevention Plans for Healthcare Associated (HCA) Legionella Disease (LO) - August 2014
- Procurement, Processing and Administration of Blood and Blood Components VAMHCS 512-113/PL-005

I. Assessments – Internal and External

1. The Quality Management Plan (includes quality monitors and related internal assessments) asks, "How well are we doing and are we in compliance with regulatory requirements?"

    a. The Process Control Monitors (aka quality monitors) are summarized in the Monthly QA-Performance Improvement Monitors which lists all current monitors for each section and identifies at a glance the function, dimension of care and regulatory requirement of each. This list is reviewed on a yearly basis by the QM technologist, supervisors, the lab manager and the P&LMS Medical Director.

        1) Results of monitors are reviewed at least monthly and shared with applicable staff.

        2) When targets (if defined) are not met, there is documented follow-up.

        3) Improvement activities or delays to such are also documented and shared as appropriate.

    b. These quality monitors help to gauge the effectiveness of process control and the lab's contribution to patient care. All critical functions will be encompassed in these assessments, but a specific area may be targeted at a given time based on indicators suggesting that a particular process may be out of control.

    c. Most monitors are developed to facilitate benchmarking of performance measures and will:

        1) Ensure that operational activities meet predetermined standards and are in compliance with applicable regulations.
        2) Identify opportunities for improvement (OFI) and may provide a basis for process improvement.
        3) Encompass activities in all phases of testing (pre-analytic, analytic and post-analytic), for all services and during all shifts.
        4) Change over time depending on results and requirements.

2. Internal Audits: Comprehensive internal audits are performed by P&LMS.

    a. This is accomplished by reviewing the current CAP checklist during our interim self-inspection and through direct observation of staff performing key functions.

    b. These audits are designed to:

        1) Determine the effectiveness of the Quality management System.

2) Identify opportunities for improvement (OFI) and may provide a basis for process improvement.
3) Monitor the adequacy of each SOP and operational compliance with, or any deviations from, SOP(s).
4) Ideally, these audits are performed by (an) individual(s) who is/are not directly responsible for the process being audited.
5) Thresholds and/or expected performance will be defined for each audit.

3. External Assessments / Inspections: P&LMS undergoes periodic external inspections at defined intervals that are either required by regulation, accreditation, and licensure or invited on a voluntary basis by the facility. P&LMS is assessed by the following regulatory or accrediting agencies:

   a. The College of American Pathologists (CAP), including biennial interim self-inspections.
   b. The Joint Commission (TJC) as part of the facility inspection.
   c. Food and Drug Administration (FDA).
   d. VHA Regional Commissioner.
   e. American Association of Blood Banks (AABB)

4. External Assessments / Proficiency Testing: P&LMS participates in a proficiency-testing program in order to compare its testing results with those of a peer group of laboratories of comparable complexity. This testing is an important external audit that also assesses process control, quality and staff competency.

   a. The laboratory is enrolled in proficiency testing programs that are appropriate for its level of testing and meets CLIA '88 and other regulatory and accreditation requirements / standards.
   b. Proficiency testing samples are handled as routine patient samples. Bench technical staff uses routine methods to perform the testing.
   c. Supervisory Medical Technologists, Staff Pathologists, Quality Management Technologist and the Lab Manager and/or Medical Director of P&LMS actively review and evaluate the results of proficiency testing and take appropriate corrective action steps as necessary. Survey results are shared with bench staff for review, education and input.
   d. Documentation is maintained of all aspects of the proficiency-testing program including dates, observed results, identification of individuals performing the tests, interpretation, supervisory and medical director review and corrective actions, if any.

5. Laboratory Management Index Program (LMIP)

   P&LMS participates in the CAP LMIP program that compares productivity, utilization and cost-effectiveness indicators to a peer group of laboratories. The Lab Manager, Staff Pathologists and Section Supervisors evaluate the data and make recommendations for improvement.

6. Transfusion Utilization Review Committee (TURC)

   a. The Transfusion Committee is a peer-review program that monitors transfusion practices for all categories of blood and blood components.
   b. The committee meets quarterly to communicate important transfusion issues to providers through the Division Director to the Executive Committee of the Medical Staff (ECMS).

7. Documentation and follow-up
   Results of the aforementioned assessments are reviewed. Reports are prepared detailing the findings, any problems identified, any corrective actions taken and to determine the need for process improvement. The reports are then forwarded to the Laboratory Medical Director or designee for internal approval. Also the reports are forwarded for approval to the facility's Office of Quality, Safety and Improvement (QSI) and discussed at the monthly Quality Management meetings (QMM). The results are also reported to institutional multidisciplinary committees (i.e. Accreditation and Transfusion Committee, Surgical and Other Invasive Procedure Review Committee, Risk Management) for further action, if needed. An annual review of all assessments will be prepared.

APPLICABLE DOCUMENTS AND PROCEDURES: **I. Assessments**

- Proficiency Testing Enforcement Procedures, VHA Handbook 1106.1, Chapter 16
- P&LMS SOP: Performance of Proficiency Testing Assessment (Gen 00005)
- P&LMS SOP: Laboratory CAP Interim Self Inspections Procedure (Gen 00004)
- P&LMS SOP: CAP Compliance and Proficiency Testing Challenges (Gen 00005)
- P&LMS SOP: Semi-Annual Documentation of Analytes Not Covered by CAP (Gen 00002)
- CAP Laboratory Activity Menu
- Quality Management Report

J. Process Improvement

1. Continuous Quality Improvement/Risk Management (CQI/RM) Program

   a. Goal and Philosophy: The overall goal of the service CQI/RM program is to provide a planned, ongoing comprehensive mechanism for monitoring and evaluating services rendered as it relates to quality appropriateness, use of resources and risk/safety factor relating to patients and service members. To accomplish this, all staff members will assert a commitment to quality and be alert to opportunities to improve services and to identify educational needs for themselves and patients. All staff members within the service are required to participate in the medical center and the service's CQI RM program.

   b. Assignment of Responsibility: The Medical Center Director has overall responsibility for CQI/RM that he has delegated to the CEB through the Chief of Staff as the medical center's CQI/RM Committee. At the service level, specific responsibilities are assigned as follows:

      1) The Service Chief is responsible for implementing and administering the service CQI/RM program in a consistent integrated fashion with the medical center CQI/RM Staff Committee. The Chief or designee is responsible for reporting to the Medical CQI/RM Staff Committee on a quarterly basis.

      2) The QM technologist is responsible for collecting CQI/RM data. After review by the Chief and Staff, he/she reports to the Medical Center CQI/RM and other committees as may be required.

      3) Section Chiefs and supervisors are responsible for collecting CQI/RM data within their sections and reporting to the QM technologist.

      4) All staff members are responsible for assuming delegated responsibilities and continually contributing to the improvement of the CQI/RM program in the following, but not limited to, activities:

         a) Collection and maintenance of practitioner specific data for assessment and re-privileging purposes.

         b) Participation in intra/inter-disciplinary activities.

         c) Sharing of data and interfacing with the other services and committees.

         d) Adherence to the confidentiality regulations outlined in Title 38, U.S.C. 3305, M-I., Part 1.

         e) Compliance with the medical center-wide CQI/RM plan and directives.

c. Definition of Scope of Service

Pathology and Laboratory Medicine Service provides the medical center a variety of analyses of patient specimens in the following areas Anatomic pathology, chemistry, hematology, blood banking, microbiology, urinalysis and serology. A portion of the specimens that are analyzed are drawn by our inpatient/outpatient phlebotomy team. Typically, the procurement, accessioning, performance, and reporting of laboratory tests are the general scope of the service.

d. Major Aspects of Service that Merit Monitoring and Evaluation:

1) Resource utilization
2) Safety
3) Problem/risk identification
4) Staff education
5) Interpretation of diagnostic test results
6) Appropriateness of test requests
7) Quality control

e. Indicators Related to Major Aspects of Service

A list of CQI/RM indicators has been developed. Each of these indicators addresses one or more major aspect of service rendered by Pathology and Laboratory Medicine Service. This list is meant to guide the selection of a manageable number of indicators, but does not preclude the designation of additional indicators as circumstances dictate.

f. Thresholds for CQI/RM indicators

All indicators have been assigned thresholds that if exceeded would necessitate particular attention towards ascertaining the causes and implementing corrective actions. However, even if a threshold is not exceeded, all exceptions are to be examined for any trends and or information that may suggest opportunities to improve sections. Any instances of noncompliance with an indicator will be tracked and trended to determine whether there is a need for a more focused evaluation to identify opportunities to improve care and services.

g. Collection and Organization of Data

1) Section Chiefs and/or Supervisors will collect CQI/RM data. Staff physicians and/or resident physicians will perform medical review when necessary.

2) Data will be primarily obtained from medical record review, the medical center DHCP, laboratory logs, work lists, workload sheets, communication forwarded from other services, committees, or functions throughout the medical center. This would include logs, UR reports, direct observation of staff, incident reports, preventive maintenance records, and any other communication that is deemed pertinent with regards to the overall goal of the service CQI/RM.

3) Each ongoing indicator will be evaluated at the monthly staff CQI/RM meeting and significant and/or interdisciplinary information presented quarterly to the ECMS meeting.

4) Tracking and trending data are periodically evaluated to determine if further evaluation is needed, i.e. whether to continue to gather data for an indicator that may no longer be needed, useful, or informative.

h. Evaluation Procedure When Thresholds are exceeded

Although all noncompliance for any indicator is analyzed, particular attention is paid to those indicators that exceed their respective thresholds. An evaluation by a qualified staff member will be conducted to determine the cause of the variance. As is relevant, patterns or trends in service that relate to specific units, specific skills, personnel, groups of people (patients, practitioners), other services, operational processes, policy/procedures, regulations, and/or the practice or behavior of people (patients, practitioners), or of an individual will be examined. A single individual will conduct the investigation and report the findings to the Chief and present at the following monthly CQI/RM meeting. The goal of investigation and recommendations will be to identify opportunities to improve services.

i. Implementation of Action Plan

Quarterly indicators that have not exceeded threshold or provided an opportunity to improve service will be evaluated for appropriateness of threshold, data collection method, and monitoring evaluation procedures to determine their effectiveness and or usefulness in assessing quality and appropriateness of service. At each monthly CQI/RM meeting, an action plan for indicators that exceed threshold or showing a trend in sub threshold noncompliance will be developed. A plan of action shall consist of the following components:

1) Who is responsible for implementation?
2) Specific actions to be implemented
3) Expected change subsequent to implementation
4) Time interval in which action is expected to have desired impact.

j. Assessment of the Success of Action Plan

In general, the success or failure of an action plan will be determined by continuing to monitor the indicator that originally detected the problem area. Ad hoc or supplemental indicators may be followed as necessary depending upon the scope that may consist of permanent installation of the action plan or formulating and implementing a different action plan. In any case, the situation will continue to be monitored for at least 6 months after the action plan has been successful to determine the permanence of the correction.

k. Communication of Relevant Service CQI/RM Program to the Medical Center wide CQI/RM Program

1) This is accomplished by:

a) Documenting service CQI/RM findings, conclusions, recommendations, actions, and evaluations/ follow-ups in the service minutes, which are forwarded through the CQI/RM process to the CEB that serves as the medical centers CQI/RM Committee on to the Director for final review and approval.
b) Providing regular reports on CQI/RM activities to the Quality Management Office schedule and in a format approved by the CEWB for integration into the CQI/RM program process.
c) Providing an annual assessment on the quality and effectiveness of the service CQI/RM program.
d) Receiving and generating referrals on CQI/RM issue/problems to and from other services, functions, and committees.
e) Participating in intra/inter-disciplinary CQI/RM activities throughout the medical center, and where applicable and directed, other facilities within or outside the VA system
f) Integrating practitioner-specific data into CQI/RM processes for credentialing privileging, reassessment, and re-privileging purposes and/or periodic performance evaluation of other health care professionals.
g) Providing informational feedback to the staff. Integration of CQI/RM data into the center wide program contributes to the detection of trends, performance patterns, and potential problems that affect more than one service and can result in patient care/service improvement if those services work together in its resolution.

l. Department Meetings/Minutes

Monthly meetings and minutes will be submitted in the format approved by the CEB and Director: Issues, Findings, Conclusions, Recommendations, Action and Evaluation (follow-up).

m. Confidentiality

All CQI/RM data and materials generated for such purposes are to be marked CONFIDENTIAL with a specific reference to it being peer review data protected under 38 U.S.C. 3305, M-1, Part 1. Materials may not be transmitted to anyone without proper consent or authorization as provided by law, regulation, or medical policy.

n. Annual Review of Service Plan and Program

Review is required in compliance with the center wide CQI/RM program plan. The annual review will follow the CEB approved format and will be forwarded through the CQI/RM processes to the CEB. The CQI/RM report will be integrated into the annual management briefing with the Medical Center Director.

o. Compliance to Center wide CQI/RM Plan

Service will make every effort within its resources to comply with the center wide CQI/RM plan.

p. Affirmation Statement

By signature and submission of this plan, the Service Chief acknowledges and accepts the responsibility delegated by the Director for the conduct and effectiveness of this service CQI/RM program.

q. Conflict of Interest Statement

No practitioner may participate as a reviewer in a case in which they were professionally involved in any capacity.

r. Continuing Education

Service Chief is responsible for providing and/or identifying access to opportunities for continuing education of the service staff. The Service Chief is also responsible for facilitating staff attendance at mandated educational programs on safety, infection control, and fire safety.

s. Guide to Available CQI/RM Monitors-Indicators for P&LMS

Note: Not all of these monitors are in use at any time. Monitors may be added or deleted as required. This is a guide to some of the recent monitors.

Section	Monitor/Indicator	Acceptable Threshold
General (All Sections)	**Proficiency testing surveys from CAP (College of American Pathologists)**	**>95% acceptable overall**
	Critical Values Reported	>95%
	Result Read Back Documented	>95%
	STAT Test TAT (Troponin I, CBC, PT/PTT, U/A and Urine Pregnancy) for all shifts	>95% <60 minutes
	Specimen Labeling	100%

Section	Monitor/Indicator	Acceptable Threshold
Chemistry	STAT TAT Troponin I	>95%

Section	Monitor/Indicator	Acceptable Threshold
Microbiology & Serology	Contaminated Blood Cultures	<3% of submitted specimens
	Rejected specimens	95%
	TAT of test results: Admission MRSA testing And Chromagar testing	100% <3 hour TAT.

Section	Monitor/Indicator	Acceptable Threshold
Hematology/Coagulation	Acceptable Specimens (PT/PTT)	>95%
	STAT TAT PT/PTT, CBC and Urinalysis STAT Urine Pregnancy	>95%, <60 minutes <30 minutes

Section	Monitor/Indicator	Acceptable Threshold
Anatomic Pathology / Surgical Path/ Cytology	Completion of Autopsies within 48hr	100%
	(VHA): Final autopsies completed within 30 days	>90%
	(CAP): Final autopsies completed within 60 days	100%
	TAT: Surgicals reported within 5 working days	90%
	TAT: GYN and NON-GYN Cytology within 2 days Specimen Labeling	90% 100%
	TAT: Frozen section specimens completed within 20 minutes	90%
	Frozen & Final Diagnosis read back	100%
	Consult Agreement – Surgical	100% correlation
	Consult Agreement – Cytology	100% correlation
	Cancer Pathology Reports	95% following synoptic report

Section	Monitor/Indicator	Acceptable Threshold
Transfusion practices	Acceptable labeling	100%
	ABO/Rh confirmatory testing performed	100%
	FDA Reportable Blood Product Deviations – Investigated & Remedial actions taken	100%
	Transfusion reactions	100%
	C:T Ratio	2

Section	Monitor/Indicator	Acceptable Threshold
Perry Point Core Lab	Documentation of Critical Values in Vista	95%
	Documentation of "Read-Back"	95%
	POC Glucose Critical Value / Comment in CPRS	>90%
	STAT Test TAT (Troponin I, CBC, PT/PTT, U/A)	>95%
	Phlebotomy Outcomes: # acceptable orders in Vista (+/- 60 days)	≥90%
	Manual Result Entry Error Detection: % of correctly reported results	100%
	Correctly Labeled Specimens	>95%
	Coagulation: Acceptable specimens received	>95%
	Chemistry: Acceptable specimens received (without hemolysis)	>95%
	Blood Bank: Acceptable specimens received (acceptable labeling)	100%

	Monitor/Indicator	Threshold
Ancillary Testing	Glucose Critical Value/Comment documented in CPRS	>90%

APPLICABLE DOCUMENTS AND PROCEDURES:

J. Process Improvement

- ❖ Quality Improvement/Risk Management Program
- ❖ Path and Lab Supervisor Meetings Minutes
- ❖ Summary List of Current Internal Monitors
- ❖ Data Collection and Organization

K. Safety

P&LMS adheres to the medical center policies and procedures and its own Safety Manual and Chemical Hygiene Plan. These policies and procedures meet the requirements of OSHA, FDA, EPA, NFPA AND pertinent CFRs and are readily available to all staff in the VAMCHS intranet site. These policies address how and what to document and report in the following general concerns:

1. Fire protection and control
2. Electrical safety
3. Standards for handling of hazardous materials (e.g., chemicals, carcinogens, blood borne pathogens, poisons, compressed gases)
4. Infection control/universal precautions
5. Waste disposal, segregation of biohazards and sharps
6. Injury/accident management
7. Security
8. Disaster preparedness
9. Personal protective equipment
10. Tuberculosis

APPLICABLE DOCUMENTS AND PROCEDURES: **K. Safety**

- P&LMS Chemical Hygiene Plan VAMHCS 113/PL-008
- P&LMS Safety Plan VAMHCS 113/PL-006

L. Customer Service

Customer service and satisfaction are measureable aspects of quality.

1. P&LMS has identified its customers (both internal and external) and their needs and expectations.
   a. Customer concerns must be included when introducing new or redesigning old processes.
2. There are documented customer feedback mechanisms, both formal and informal.
3. Complaints are documented, managed and/or resolved.
4. Customer satisfaction surveys have been implemented.
   a. Prior approval is obtained, as needed.
   b. Final reports are prepared for management review.
5. Issues are referred for process improvement, as needed.

APPLICABLE DOCUMENTS AND PROCEDURES: **L. Customer Service**

- P&LMS SOP: Reporting of Incidents and Safety Concerns (Gen 00010)
- P&LMS SOP: Communication Policy (Gen 00020)
- Phlebotomy Patient Satisfaction Survey
- Path and Lab Staff Meeting Minutes- Per Laboratory Section