

PATHOLOGY AND LABORATORY MEDICINE SERVICE (P&LMS) PROCEDURES

1. REASON FOR ISSUE: This Veterans Health Administration (VHA) Handbook is issued to provide procedures for the administration, accreditation, staffing, and functioning of clinical and anatomic pathology laboratories in Department of Veterans Affairs (VA) facilities or facilities managed by VA.

2. SUMMARY OF MAJOR CHANGES: This VHA Handbook contains implementation instructions for VHA Directive 1106. The following procedures for the administration, accreditation, staffing, and functioning of clinical and anatomic pathology laboratories in VA facilities or managed by VA facilities have been updated:

- a. Paragraph 3: New definitions paragraph.
- b. Paragraphs 5.a., b., and c.: Responsibilities for National Director Pathology and Laboratory Medicine Service, National Enforcement Officer, and Regional Commissioner have been defined.
- c. Paragraphs 5.d., e., and f.: Responsibilities for the Facility Director, Chief of Staff, and Veterans Integrated Service Network (VISN) Director have been extracted from the document and placed in the new responsibilities paragraphs.
- d. Paragraph 5.g.(23): Clarified the role and responsibilities of contracted pathologists and the oversight responsibilities of the VA in compliance with government regulations.
- e. Paragraphs 6, 7 and 8: Clinical Laboratory Improvement Amendments (CLIA) requirements, proficiency testing requirements, and accreditation requirements have been extracted from throughout the handbook and placed in separate paragraphs. Defined laboratory director requirements. Clarified CLIA application requirements.
- f. Paragraph 13. f.: Revised patient self-testing requirements consistent with new VHA patient self-testing policies.
- g. Paragraph 15 (1) (c)-(d): Revised qualification requirements for individuals performing anatomic pathology reports.
- h. Paragraph 17 and Appendices: Removed references to Special Reference Laboratory for Pathology at Armed Forces Institute (AFIP) and the Systematic External Review of Surgical (SERS) cases program. Replaced the paragraph and appendices with information on the new VHA agreement with the Joint Pathology Center (JPC).
- i. Paragraph 19: Incorporated regulatory changes to the select agent security requirements.
- j. Appendix D: Added new appendix on personnel standards according to the requirements outlined in this Handbook and the federal regulations.

k. Revised autopsy requirements consistent with VHA Directive 2011-019, The Autopsy As A Critical Component Of Quality Management

4. RELATED ISSUES: VHA Directive 1106.

5. RESPONSIBLE OFFICE: The National Director, Pathology and Laboratory Medicine Service (P&LMS), Diagnostic Services (10P4D) is responsible for the contents of this Handbook. Questions may be addressed to (202) 632-8418.

6. RESCISSIONS: VHA Handbook 1106.1, dated October 8, 2008, is rescinded.

7. RECERTIFICATION: This VHA Handbook is scheduled for recertification on or before the last working day of January 2021.

David J. Shulkin, M.D.
Under Secretary for Health

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CONTENTS

PATHOLOGY AND LABORATORY MEDICINE SERVICE (P&LMS) PROCEDURES

1. PURPOSE:.....	1
2. BACKGROUND:.....	1
3. DEFINITIONS:.....	1
4. SCOPE:.....	4
5. RESPONSIBILITIES:	7
6. VA NATIONAL ENFORCEMENT PROGRAM CLIA APPLICATION PROCESS: .	18
7. ACCREDITATION:.....	22
8. PROFICIENCY TESTING:	24
9. P&LMS NATIONAL ENFORCEMENT PROGRAM PROTOCOL:	30
10. CATEGORIZATION OF SPECIFIC LABORATORY TEST SYSTEMS, ASSAYS, AND EXAMINATIONS BY COMPLEXITY:.....	31
11. TESTING PERSONNEL:.....	32
12. QUALITY MANAGEMENT PROGRAM (QM):.....	32
13. ANCILLARY TESTING:.....	37
14. IMMUNOHEMATOLOGY, BLOOD TRANSFUSIONS, AND TRANSFUSION MEDICINE TESTING:	42
15. SURGICAL PATHOLOGY, CYTOPATHOLOGY AND ELECTRON MICROSCOPY TESTING:	56
16. POST-MORTEM EXAMINATION:.....	78
17. JOINT PATHOLOGY CENTER (JPC) REFERENCE LABORATORY SERVICES:	85
18. INFECTIOUS DISEASES, INFECTION CONTROL, AND EPIDEMIOLOGY:	87
19. BIOSECURITY AND BIOSAFETY PROCEDURES:	88
20. ENVIRONMENTAL AND SAFETY ISSUES IN THE LABORATORY:.....	94
APPENDIX A	1
POST-MORTEM QUALITY ASSURANCE SURVEY (Autopsy Review)	1
APPENDIX B	2
FORMER PRISONERS OF WAR (POWs), AGENT ORANGE/VIETNAM SERVICE VETERANS, KUWAIT/PERSIAN GULF WAR VETERANS, OPERATION IRAQI	

FREEDOM/IRAQ SERVICE VETERANS, AND OPERATION ENDURING	
FREEDOM/AFGHANISTAN VETERANS.....	2
APPENDIX C	1
GUIDANCE FOR REQUESTING AN AUTOPSY	1
APPENDIX D	1
VA PERSONNEL REQUIREMENTS BY TEST COMPLEXITY.....	1

PATHOLOGY AND LABORATORY MEDICINE SERVICE PROCEDURES

1. PURPOSE

This Veterans Health Administration (VHA) Handbook provides procedures for the administrative structure and management of services and service lines providing laboratory testing in Department of Veterans Affairs (VA) facilities and their outreach functions. The Handbook further defines requirements unique to VA. **AUTHORITY:** Public Law 100-578 (1988), Public Law 102-139 (1991), and 42 CFR Part 493.

2. BACKGROUND

a. In 1988, Congress passed the Clinical Laboratory Improvement Amendments (CLIA) as part of the Public Health Service Act (Title 42 United States Code (U.S.C.) 263a). These amendments codified into law requirements for the staffing, management, procedures, and oversight of United States (U.S.) laboratories that perform testing used in the diagnosis, treatment, and prevention of disease in patients. The Department of Health and Human Services (HHS) then published implementing regulations for CLIA under Title 42, Code of Federal Regulations (CFR) Part 493.

b. In 1991, Congress passed Public Law (Pub. L.) 102-139, Sec. 101(a), which exempted VHA from CLIA and stated that the Secretary of Veterans Affairs would, in consultation with the Secretary of HHS, publish regulations that would “establish standards equal to that applicable to other medical facility laboratories in accordance with the requirements of Section 353(f) of the Public Health Service Act.”

NOTE: *This requires VA laboratories to meet the requirements of CLIA, but left the enforcement and oversight of the regulations to VA.*

c. This Handbook supplements 42 CFR Part 493 for those areas where VA regulations do not provide explicit guidance.

3. DEFINITIONS

a. Administrative Laboratory Chief.

(1) In situations when a qualified pathologist cannot be successfully recruited to serve as the Chief or Director, Pathology and Laboratory Medicine Service (P&LMS) in the P&LMS Service-line, a non-pathologist Administrative Laboratory Chief must be appointed to perform the laboratory director functions and to provide direction and oversight whenever a technical consultant is retained (e.g., consulting pathologist). The Administrative Laboratory Chief will serve as the laboratory director (signer of the CLIA application) and therefore must meet the laboratory director personnel qualifications for the appropriate laboratory complexity according to laboratory accreditation requirements, this Handbook (paragraph 6.c. and Appendix D), and as outlined in the laboratory director personnel standards in 42 CFR Part 493, Subpart M.

(2) The Administrative Laboratory Chief must be aligned under the oversight of a VA pathologist who serves in the P&LMS service-line (e.g., aligned under a Chief or

Director, P&LMS at a VA medical facility or under a pathologist service-line Chief or Director at the Veterans Integrated Service Network (VISN) level). Testing decisions must be made by a pathologist in the P&LMS service-line.

b. **Ancillary Testing.** Ancillary testing is laboratory testing performed within and under the administration of the VA medical facility, health care system, or its outreach functions (clinics, etc.), but outside the physical facilities of the main clinical laboratory. This includes all laboratory testing sites, such as point of care testing, satellite or specialty laboratories, community-based outpatient clinic (CBOC) testing sites, and home-based health care (HBHC) when such testing is performed by a VA employee. Ancillary testing includes all laboratory testing sites that fall under the auspices of the main parent facility even when they may be under a separate laboratory director, CLIA registration number, or separate accreditation.

c. **Autopsy Review.** An autopsy review is the comparison of pre-mortem diagnoses and diagnostic assessment procedures with post-mortem diagnoses and other autopsy findings to assess diagnostic accuracy. This process is covered by 38 U.S.C. 5705 and its implementing regulations.

d. **Blood Management Principle.** Blood Management Principle is the appropriate use of blood and blood components, with the goal of minimizing their use.

e. **Blood Utilization Review/Transfusion Utilization Chair.** The Blood Utilization Review/Transfusion Utilization Chair is the individual appointed by the VA medical facility Director responsible for the oversight of blood product usage review.

f. **Blood Utilization Review.** The Blood Utilization Review is a review of all aspects of blood services to determine whether blood and blood products are appropriately ordered and stored, delivered, and provided in a safe, timely, and therapeutic manner. Evaluation of transfusion errors and reactions is included. This process is covered by 38 U.S.C. 5705 and its implementing regulations.

g. **Chief or Director, P&LMS.** The Chief or Director, P&LMS directs and coordinates the patient care, administration, education, and research functions of the P&LMS service-line and provides oversight for all laboratory testing performed under the medical center/health care system and CBOC laboratory CLIA number(s) including ancillary testing sites, specialty labs, HBHC testing sites, or research labs performing testing used for patient care.

h. **High Complexity Testing.** High complexity testing refers to the most complicated laboratory tests requiring the most rigid testing requirements outlined in the CLIA regulations. Test complexity is determined by the Food and Drug Administration (FDA) according to the criteria outlined in the 42 CFR 493.17. Testing sites performing high complexity testing must obtain a high complexity CLIA certificate.

i. **Infection Control Review.** Infection Control Reviews are surveillance activities to identify and monitor the rate of nosocomial infections. This process is covered by 38 U.S.C. 5705 and its implementing regulations.

j. **Laboratory Director.** The laboratory director is the individual designated on the CLIA certificate as the laboratory director and is the individual responsible for all aspects of laboratory testing performed under that CLIA certificate.

k. **Laboratory Test.** A laboratory test is an examination, diagnostic, or monitoring procedure on a human specimen removed from the body to determine specific information for diagnosis, treatment, or prevention of disease, and to detect the impairment of health status, or to assess the health of human beings.

l. **Moderate Complexity Testing.** Moderate complexity testing is the rating given by the FDA to commercially marketed *in vitro* diagnostic tests based on their risk to public health level. The complexity is determined based on the scoring criteria outlined in 42 CFR 493.17. Testing sites performing moderate complexity testing must obtain a moderate complexity CLIA certificate.

m. **Mohs Surgery.** Mohs Surgery is the procedure for microscopically-controlled removal of skin tumor developed by Frederic E. Mohs.

n. **Non-waived Testing.** Non-waived testing refers to tests categorized as either moderate complexity (including provider-performed microscopy) or high complexity by the FDA, according to a scoring system used by the FDA.

o. **Peer Review for Quality Management.** A Peer Review for Quality Management is a critical review of care performed by a peer or group of peers. Peer review processes are protected under 38 U.S.C. 5705 and its implementing regulations. A quality management review may be used to prompt a performance review. However, since a peer review for quality management is protected, it cannot be substituted for a performance review.

p. **Performance Reviews.** A performance review is any review that is conducted for purposes other than quality improvement related to decisions affecting individual providers. Performance reviews are not protected under 38 U.S.C. 5705. Examples that fall under this classification are: Administrative Investigation Boards and Ongoing Professional Practice Evaluations.

q. **Point of Care Testing.** Point of care testing refers to tests designed to be used at or near the site where the patient is located, and that are performed outside the physical facilities of the clinical laboratory.

r. **Privileged Provider.** A privileged provider is an individual who meets the personnel qualifications for provider performed microscopy (PPM) as defined in the CLIA regulations, 42 CFR 493.1363 and is privileged by the medical center to perform laboratory testing as part of their clinical scope of practice. The CLIA PPM testing personnel qualifications are outlined in Appendix D, paragraph 2.c. of this Handbook.

s. **Proficiency Testing.** Proficiency Testing (PT) is a program in which samples with unknown values are periodically sent to a laboratory for analysis in which each

laboratory's results are compared with peer laboratories and reported to the participating laboratory and the VA National Enforcement Program.

t. **Provider Performed Microscopy Testing.** Provider performed microscopy (PPM) testing refers to a subset of specific moderate complexity light microscopy procedures outlined in the CLIA regulations, which a physician, midlevel practitioner, or dentist performs on a specimen obtained from the provider's own patient.

u. **Select Agents.** Select agents are biological agents and toxins that could pose a severe threat to public or plant health, or to animal or plant products.

v. **Specialty Laboratory.** A specialty laboratory is a laboratory dedicated to a single specialty of testing or esoteric testing.

w. **Testing Site.** A testing site is any location where laboratory testing is performed (waived or non-waived) when such testing is used in the diagnosis, treatment, or assessment of patients within the VA health care organization and outreach functions. This includes any testing that may occur outside the physical facilities of the main laboratory.

x. **Transfusion Medical Director.** A Transfusion Medical Director is the individual responsible for the medical and technical oversight of the transfusion service.

y. **VA Laboratory.** A VA laboratory is any site within a VA medical facility or its ancillary testing sites that performs laboratory testing used in the diagnosis, treatment, or assessment of patients.

z. **Waived Testing.** Waived testing refers to a category of tests defined as simple laboratory examinations. Testing sites performing waived tests must obtain a VA CLIA certificate for minimal complexity testing.

4. SCOPE

a. This Handbook applies to the VA Central Office (VACO), VISNs, P&LMS Program Office, National Enforcement Program Office, Regional Commissioner's Offices, VA medical facilities, and supported medical facilities. This is both a reference document and management tool for leadership, medical staff, laboratory professionals, and stakeholders at all levels in VHA to develop and maintain a system to support quality health care delivery to Veterans.

b. P&LMS provides the principal medical diagnostic laboratory testing and transfusion functions in all VA medical facilities and sets the standards for quality, test methods, and procedures for laboratory testing for patient care in the VA medical facility and supported clinics.

c. All laboratory testing within VA used for the diagnosis, treatment, and prevention of disease in patients must be provided in compliance with the requirements outlined in this Handbook and 42 CFR Part 493, CLIA.

(1) These standards must be met for any laboratory service offered within a VA medical facility and outreach clinics, regardless of the physical relationship to the main P&LMS or the administrative service assigned to direct the personnel, research, or technical aspects of the testing site.

(2) The same standard must be met for contracted laboratory services performed on site at VA laboratories, outreach clinics, or testing sites.

d. Laboratory testing, where applicable, must also meet the requirements of the following organizations:

(1) The Joint Commission;

(2) College of American Pathologists (CAP);

(3) AABB (formerly the American Association of Blood Banks);

(4) FDA;

(5) Occupational Safety and Health Administration (OSHA); and

(6) Nuclear Regulatory Commission (NRC).

e. All VA laboratories, including CBOC sites performing waived and PPM testing, are required to register with the P&LMS National Enforcement Program in VACO, Washington, DC, and must be assigned a CLIA number as outlined in the interagency agreement between the Center for Medicare and Medicaid Services (CMS) and VA.

f. All laboratory testing, regardless of location, must undergo an on-site inspection by a VA-designated accrediting agency as outlined in paragraph 7 of this Handbook.

g. When the requirements of the accrediting agency and VA requirements differ, the more stringent requirements apply.

h. All laboratory testing, regardless of complexity level or where it is performed, must be under the oversight of the Chief or Director, P&LMS.

(1) Chief or Director, P&LMS is required to provide oversight for all laboratory testing performed under the medical center and CBOC laboratory CLIA number(s) including ancillary testing sites, specialty labs, or research labs performing testing used for patient care.

(2) The Chief or Director, P&LMS is responsible for all aspects of laboratory testing performed under the laboratory's accreditation umbrella and testing under the CLIA certificates for which the Chief or Director, P&LMS serves as the laboratory director.

(3) The Chief or Director, P&LMS may choose to remove waived or PPM testing performed by privileged providers from underneath the accreditation umbrella of the laboratory. These testing sites must obtain their own separate VA CLIA numbers

issued through the P&LMS National Enforcement Program. While the Chief or Director, P&LMS is not responsible for the results released by the provider, the Chief or Director, P&LMS must provide guidance for performing these laboratory procedures and ensure that they are carried out in compliance with 42 CFR Part 493 and current VHA policies.

NOTE: *Minimal testing guidance for all laboratory procedures within VHA is provided in paragraph 13.h. of this Handbook.*

i. The main clinical laboratory in each VHA health care network and each VA medical facility must be directed by a Chief or Director, P&LMS who is a licensed pathologist and board certified in anatomic pathology and/or clinical pathology by the American Board of Pathology. The clinical laboratory and anatomic pathology services are under the direction of the Chief or Director, P&LMS. This individual must have the appropriate training and background to meet the requirements of 42 CFR 493.1443 and must be able to discharge the responsibilities cited in 42 CFR 493.1445 and this Handbook.

NOTE: *The administrative separation of organizational sections providing anatomic pathology, blood transfusion, and clinical pathology services is not permitted in a VA medical facility or its outreach functions.*

j. Specialty laboratories that fall outside the accreditation umbrella of the main laboratory may have a non-pathologist physician or an individual with a doctoral degree in biological science appointed to serve as the laboratory director.

(1) This individual must be qualified by virtue of documented training, expertise, and experience in the area of analytical testing, and biological, chemical, or clinical science specifically related to the laboratory testing site's special testing functions.

(2) This individual must meet the laboratory director qualifications required by 42 CFR Part 493, Subpart M and must be able to discharge the responsibilities cited in 42 CFR Part 493, Subpart M, and this Handbook.

(3) The appointment must be approved by the local Chief or Director, P&LMS and the National Enforcement Officer.

(4) The Chief or Director, P&LMS must serve as a consultant for these specialty laboratories and ensure that testing is carried out in compliance with 42 CFR Part 493 and current VHA policies. Testing should be overseen under the ancillary testing program.

k. The scope of testing and services provided in anatomic and clinical pathology is to be appropriate for the nature of the patient care services at the facility. P&LMS either performs those tests and services required to provide quality care to patients or arranges for these services to be performed by an accredited laboratory.

l. Research laboratories within VHA are not allowed to report laboratory results that are used for diagnosis, treatment, and prevention of disease in patients, unless they are properly accredited and meet all requirements of 42 CFR Part 493.

5. RESPONSIBILITIES

a. National Director, Pathology and Laboratory Medicine Service.

(1) Reports to the Chief Consultant, Diagnostic Services under the direction of the Office of Patient Care Services (PCS).

(2) Provides guidance and recommendations to senior leadership for the establishment of VHA national policies applicable to all VA sites performing patient laboratory testing.

(3) Provides P&LMS guidance to VHA senior leadership and the VA laboratory community to ensure that timely, cost effective, and high quality anatomic and clinical pathology services are provided for VA patients.

(4) Provides oversight and enforcement of the policies defined in Directive 1106 and this Handbook in conjunction with the National Enforcement Officer and the Pathology Regional Commissioners.

(5) Oversees the quality of services provided by VA laboratories as well as laboratory compliance with regulatory, accreditation, and policy guidelines.

(6) Utilizes organizational resources and collaborates with the CMS, the Department of Defense (DoD), the FDA, the various accrediting organizations, and other Federal and civilian external agencies.

(7) Ensures that laboratories and testing sites are appropriately accredited by a VA-designated accrediting agency under the VA national contract as outlined in paragraph 7 of this Handbook and that the required accreditation programs are fully implemented. Arranges and monitors PT programs in anatomic pathology.

(8) Ensures that anatomic pathology testing sites participate in external quality review and PT programs for assessment in surgical pathology and cytopathology.

(9) Maintains a national database on the performance of postmortem examinations in the Veterans Health Care System. This database includes at least the monthly and annual autopsy rates for each VHA inpatient facility (acute and long-term care).

(10) Advises the VISN Directors of problems and concerns relating to the quality of the pathology and laboratory services provided and all laboratory testing performed in medical facilities under their purview.

(11) Works with the National Enforcement Officer, Pathology Regional Commissioners, and the Chief or Director, P&LMS at each VA facility to ensure that corrective action is implemented where problems which have the a potential for adverse patient outcome are identified.

b. National Enforcement Officer.

- (1) Reports to the National Director, P&LMS.
- (2) Provides oversight to assess regulatory compliance and enforcement for VA laboratory testing sites for requirements as defined in 42 CFR Part 493, this Handbook, and related VA Directives with the assistance of the VA Regional Commissioners and Regional Technologists. Provides direction to the VA Regional Commissioners and Regional Technologists on all VA laboratory enforcement matters.
- (3) Directs the VA CLIA Program and ensures that all VA testing sites are registered with the P&LMS National Enforcement Program and are issued a VA CLIA number.
- (4) Coordinates a nationwide contract for accreditation by a VA designated laboratory accreditation agency and for PT procurement in collaboration with the National Director P&LMS.
- (5) Ensures that all laboratory testing sites within the VA are accredited by a VA designated accrediting organization. Evaluates accrediting and regulatory agency summary reports and ensures appropriate corrective action if necessary.
- (6) Advises the VISN Director of problems and concerns relating to the quality of the pathology and laboratory services provided and all testing performed in medical facilities under their purview.
- (7) Ensures that all VA testing sites successfully participate in an approved PT program for each analyte and instrument or method.
- (8) Initiates focused reviews of laboratory testing sites if indicated and requires that corrective action is implemented to ensure that a high standard of service and patient care is provided.
- (9) Develops the strategic plan for the National Enforcement Program by incorporating goals, objectives, strategies, and performance measures to track and measure the extent of achieving strategic objectives of the VHA and Patient Care Services.
- (10) Develops coordinated action plans to address data management and aligns key organizational activities to VA strategic objectives.

c. VA Regional Commissioner.

- (1) Reports to the National Director, P&LMS and the National Enforcement Officer,
- (2) Provides oversight and enforcement of the policies defined in this Handbook and related directives under the direction of the P&LMS National Enforcement Officer and the National Director, P&LMS.
- (3) Ensures that all VA testing sites and laboratories are registered under the National Enforcement VA CLIA Program.

(4) Works with the National Enforcement Officer to ensure that all VA testing sites are in compliance with the inspection and accreditation requirements.

(5) Advises the P&LMS National Enforcement Officer of problems and concerns relating to the quality of the work in P&LMS and laboratory-related services.

(6) Delegates responsibilities and functions to the Regional Technologist.

d. **VISN Director.**

(1) Ensures that all laboratories or individuals performing testing used for the diagnosis and treatment of patients, transfusion medicine, and anatomic pathology are in compliance with the policies in 42 CFR Part 493, related VHA Directives, and this Handbook.

(2) Ensures that all laboratory testing sites within the VISN meet the requirements for external P&LMS accreditation.

(3) Ensures that small facilities that cannot recruit a pathologist to serve as the Chief P&LMS, align the Administrative Laboratory Chief under the oversight of a VA pathologist who serves in the P&LMS service-line (e.g., aligned under a Chief or Director, P&LMS at another VA medical facility or under a pathologist service-line Chief or Director at the VISN level).

(4) Communicates pathology and laboratory medicine management priorities and maintains a mode for communication with the VACO P&LMS Program Office to ensure alignment and coordination with national priorities.

(5) Ensures that facility action plans addressing P&LMS non-compliance with accreditation and regulatory requirements and VA regulations are implemented and completed.

(6) Ensures that VA medical facilities establishing a diagnostic Electron Microscopy (EM) Program in P&LMS prepare an application in accordance with the current requirements as outlined by the National EM Program Coordinator. The application must be transmitted through the VISN Director's Office with a statement from the medical facility Director expressing approval and certifying that the proposed EM resource will not create a redundancy.

(7) Ensures that each inpatient facility (acute and long-term care) within the VISN completes the autopsy monthly report and sends it to the National Director of P&LMS in VACO, no later than 30 days after the end of each month being reported.

(8) Ensures that autopsy reports are completed within 30 working days of the autopsy unless exception for special studies is established by the local medical staff.

(9) Ensures each medical facility has the capability to perform autopsies, whether on site or an alternative to performing autopsies at the medical facility is provided. This service may be contracted to another VA or accredited non-VA facility.

(10) Ensures that an alternative to performing autopsies at the medical facility is provided. This service may be contracted to another VA or accredited non-VA facility.

NOTE: *Establishment of Regional Autopsy Centers at VISN or multi-VISN level may provide access to a quality and cost-effective alternative.*

e. **VA Medical Facility Director.**

(1) Ensures that the applicable requirements of 42 CFR Part 493, this Handbook, and appropriate accrediting agencies are met when any laboratory patient care services are offered by VA laboratories, regardless of the physical location of the laboratory or the service or administrative structure assigned to direct the personnel or technical aspects of the test site.

(2) Ensures that the clinical laboratory is under the direction of a qualified, licensed pathologist, board certified in anatomic pathology and/or clinical pathology by an American Board of Pathology. Ensures that the Chief or Director, P&LMS possesses a broad knowledge of clinical medicine, basic medical sciences, clinical laboratory sciences, and management operations.

(3) Ensures that the Chief or Director, P&LMS is appointed as a voting member to the Clinical Executive Board or analogous medical staff committee, and all other appropriate committees.

(4) Ensures the following in a small or remote VA medical facility, when a full-time or part-time pathologist cannot be recruited to serve as the Chief or Director, P&LMS:

(a) Retains the services of a qualified, licensed consulting pathologist to fulfill the CLIA defined laboratory technical functions as cited in 42 CFR Part 493, Subpart M.

(b) Appoints a qualified individual to serve as the Administrative Laboratory Chief to provide oversight and direction for laboratory functions and to provide direction for the technical functions provided by a consulting pathologist. When a consulting pathologist is retained, the Administrative Laboratory Chief serves as the laboratory director and therefore must meet the laboratory director personnel qualifications for the appropriate laboratory complexity according to laboratory accreditation requirements, this Handbook, and as outlined in the laboratory director personnel standards in 42 CFR Part 493, Subpart M.

(c) Ensures the consulting pathologist fulfills the technical functions as cited in 42 CFR Part 493.

(d) Ensures the consulting pathologist is provided the appropriate resources to fulfill the requirements outlined in 42 CFR Part 493 and this Handbook.

(e) Assigns the consulting pathologist as a member of the Clinical Executive Board or analogous medical staff committee, and all other appropriate committees.

(f) Ensures that the consultant has an active role in the educational and staff competency programs of the institution and laboratory.

(g) Ensures that the services of the consulting pathologist are provided on a regular basis and that a written report of the consulting pathologist's evaluation and recommendations is provided with each visit.

(5) Ensures that all testing sites that perform laboratory tests categorized as moderate or high complexity are inspected and accredited by a VA-designated accrediting organization as outlined in paragraph 7 of this Handbook.

(6) Ensures that sites performing only waived testing and/or PPM procedures are inspected and accredited as part of the main laboratory accreditation or in conjunction with the main facility accreditation process.

(7) Ensures that all laboratory testing, regardless of complexity level or the physical location, is performed under the oversight of the Chief or Director, P&LMS including testing sites that may be under a separate laboratory director, CLIA registration number, or accreditation.

(8) Ensures that all ancillary testing sites are under the quality oversight or technical direction of the Chief or Director, P&LMS.

(9) Ensures that individuals performing testing meet the personnel requirements defined in 42 CFR Part 493 for the identified test complexity.

(10) Ensures that all laboratory testing performed within the facility, ancillary testing sites, and outreach clinics is performed under a current CLIA certificate of the appropriate complexity level for the testing performed.

(11) Ensures that P&LMS and all ancillary testing sites successfully participate in a CMS-approved PT program. The laboratory PT program must meet the requirements of CLIA, the accrediting agency, and VA, for all analytes for which PT is available, including waived, PPM, and unregulated analytes. For analytes for which no PT is available, an alternate method must be in place. Laboratories must perform PT at all sites and on every instrument used for patient testing, including backup instruments.

(12) Ensures that the facility has a working Blood Utilization Review Committee/Transfusion Utilization Committee and program designated that adheres to the mandates of this Handbook, associated Directives, and 38 U.S.C. 5705 and its implementing regulations and that there is a formalized comprehensive process to monitor transfusion-related activities. Appoints a Blood Utilization Review Committee/Transfusion Utilization Committee Chair who must be a physician with knowledge and experience in transfusion medicine. The Blood Utilization Review/Transfusion Utilization Chair is responsible for the oversight of blood usage review.

(13) Ensures that P&LMS providing anatomic pathology services participates in the non-gynecologic (GYN) cytopathology program designated by the National Director, P&LMS, a CMS approved GYN Cytopathology Proficiency Program, and any other such PT programs designated as mandatory by the National Director, P&LMS.

(14) Ensures that the facility laboratory participates in the VHA and CAP customized Laboratory Management Index Program (LMIP) and any other information queries or surveys initiated by the National Director, P&LMS for the purpose of needs assessment or evaluation of the effectiveness of P&LMS.

(15) Ensures that the facility Information Technology Office provides resources to laboratory information management for appropriate operator support, training, hardware, and backup procedures for computer downtime.

(16) Ensures that permission to perform an autopsy (i.e., post mortem examination) is requested in every instance when a patient dies while an inpatient at a VA facility or under the immediate care of a VA facility (such as during an outpatient or emergency care visit, or during an ambulatory care procedure). **NOTE:** *It is recommended that the physician provider responsible for the patient at the time of death be delegated with the task to request an autopsy from the surviving spouse or next-of-kin. Guidance for requesting an autopsy may be found in Appendix C.*

(17) Ensures that documentation of the request for autopsy is included in the patient's medical record. This documentation must include notation of the participants in the discussion and whether the permission was granted or denied. When permission is denied, the reasons for the denial are to be recorded in the medical record. **NOTE:** *Under certain circumstances, detailed in 38 CFR 17.170, the medical facility Director may cause an autopsy to be performed in the absence of consent from the decedent's surviving spouse or next of kin.*

(18) Ensures that autopsies on coroner and medical examiner cases are performed at VHA facilities only with the concurrent permission of both the coroner or medical examiner and the surviving spouse or next-of-kin. **NOTE:** *If the United States does not have exclusive jurisdiction over the area where the decedent's body is found, the local coroner or medical examiner will be informed. Coroner or medical examiner cases are defined by local statute, and need to be enumerated in the local facility autopsy policy.*

(19) Ensures restricted autopsy examinations (those limited to a specific area, i.e., brain and spinal cord, chest cavity, or abdominal cavity) meet the requirements for autopsy.

(20) Ensures that the results of autopsies are included in facility medical staff education and quality management programs.

(21) Ensures autopsies in cases of infection with high-risk pathogens are performed using appropriate personal protective equipment, environmental controls, and proper decontamination procedures commensurate with the biosafety precautions indicated for the known or suspected pathogen. If the Chief or Director, P&LMS cannot ensure or comply with appropriate biosafety precautions, there must be a local policy, approved by the medical staff, to guide if and how autopsies on cases of infection with high risk pathogens are conducted. This local policy must comply with all of the biosafety precautions indicated for the known or suspected pathogen, as well as with all of the other requirements of this Handbook.

f. **Chief Of Staff or Director of Clinical Services.**

(1) Ensures that the Chief or Director, P&LMS is provided with an inventory of the location and type of all ancillary testing equipment and sites where ancillary testing is performed, including bedside testing sites, methodology to be used, and the estimated number of tests to be performed annually.

(2) Ensures that VA medical facilities with no permanent pathologist have a 10 percent random retrospective second review performed for all surgical pathology, Moh's pathology, and cytology diagnoses for the purpose of quality assurance.

(a) Ensures that quality reviews are provided by a qualified pathologist (board certified, licensed, and experienced in anatomic pathology work). An individual who meets the VA requirements for a specific specialty as outlined in paragraphs 15.a.(1), (c), and (d) of this Handbook may perform a quality review within that specialty.

(b) Quality reviews must occur on at least a quarterly basis.

(c) The 10 percent review system is also mandated for contract or sharing agreement pathologists who provide surgical pathology or cytopathology diagnostic services for VA medical facilities.

(3) If Mohs surgery is performed on site and the Mohs lab is not included as part of the main laboratory accrediting process, the Chief of Staff must ensure that a 10 percent random retrospective second review is performed for all Mohs surgeries and 100 percent review is performed for any Mohs case for which a previous tissue diagnosis has not been performed by the local VA P&LMS.

(4) Ensures that all laboratory testing performed outside of the main laboratory is managed under the ancillary testing program under the oversight of the Chief or Director, P&LMS including all laboratory testing performed by providers (e.g., physicians, dentists, nurse practitioners, midwives, clinical pharmacists, and physician assistants).

(5) Ensures that when the medical center privileging process is utilized to fulfill any element of the PPM or waived testing competency assessment requirements, the provider must be privileged to perform the specific procedures (e.g., fecal occult blood, vaginal wet preps, etc.) they perform and that the tests performed are appropriate and performed within the provider's specialty. A provider cannot be privileged to perform a blanket category of procedures such as waived procedures.

(6) Ensures that there is a mechanism in place to mandate that providers or testing sites identified by the Chief or Director, P&LMS as failing to follow laboratory testing requirements are not allowed to continue performing laboratory tests on patients.

(7) In conjunction with the Chief or Director, P&LMS ensures that there is an ongoing mechanism for monitoring and evaluating the usefulness and appropriateness of referral testing, and ensures that referral testing is appropriate for patient care.

(8) When patients are to receive treatment at a VA facility based on tissue samples obtained elsewhere (either at another VA facility or non-VA facility), ensures that the patient's clinical provider obtains and submits the outside tissue slides to the VA pathologists at the facility where the patient will receive treatment so that the diagnosis can be confirmed. Any treatment or procedure on the patient should not be performed until confirmation of the diagnosis has been obtained.

(9) Provides overall management of post-mortem examination services that include:

(a) Arrangements for securing post-mortem examination authorizations. **NOTE:** *It is VHA policy that permission to perform a post mortem examination must be requested in every instance when a patient dies while an inpatient at a VA facility or under the immediate care of a VA facility;*

(b) Provision of sufficient competent staff for the examinations and for timely completion of post-mortem examination reports;

(c) Maintenance of suitable facilities and appropriate coordination with funeral directors and local authorities;

(d) Ensuring that post-mortem examination findings become a continuing component of the internal monitoring of medical practice of the VA medical facility.

g. **Chief or Director, P&LMS.** The Chief or Director, P&LMS serves as an active member of the medical staff, directing and coordinating the patient care, administration, education, and research functions of P&LMS. The Chief or Director, P&LMS, need not perform all responsibilities personally. Selected functions may be delegated to qualified pathologists, medical laboratory scientists, laboratory managers, and supervisors. Medical care responsibilities may only be delegated to physicians. Technical responsibilities may be delegated to qualified laboratory personnel, as appropriate. The Chief or Director, P&LMS, however, remains responsible for the overall operation and administration of the laboratory, ensuring that quality patient services are provided and that personnel operations and laboratory management are run efficiently and effectively.

(1) Provides consultation and guidance to health care providers regarding matters pertaining to pathology and laboratory medicine and the medical significance of laboratory findings. The Chief or Director, P&LMS, designates, in writing, which is authorized to perform pathology consultations and to document medical diagnoses and information in a patient's record.

(2) Serves as a voting member of the Clinical Executive Board, or analogous medical staff committee, and all other appropriate committees.

(3) The Chief or Director, P&LMS, or designee, participates in applicable cross-organizational performance-improvement activities, develops and communicates objectives, and coordinates efforts to integrate patient care and support services.

(4) Provides educational direction for the medical and laboratory staff and participates in educational programs of the institution as appropriate. **NOTE:** *This education may also involve many levels, including medical students, allied health students, graduate students, and residents from academic affiliates.*

(5) Directs and coordinates the functions of the service within the medical facility and all outreach clinics based upon the mission, special needs, and size of the facility. The functions of this position are diverse and encompass patient care, administration, education, and research.

(6) Provides overall operation and administration of the laboratory, ensuring that quality patient services are provided and that personnel operations and laboratory management are efficient and effective.

(7) Identifies all laboratory testing performed within the facility and its outreach clinics regardless of the complexity or where the testing is performed within the organization, and provides assistance and oversight to ensure that all patient laboratory testing performed is in compliance with 42 CFR Part 493 and VHA policies. This includes oversight responsibility for ancillary testing sites, and participation in the evaluation of test appropriateness for the institution regardless of the testing site.

(8) Ensures current accreditation of all testing sites that perform non-waived laboratory tests for patient care by a VA designated CMS “deemed” accrediting organization(s).

(9) Submits corrective actions for findings of accrediting and regulatory agency inspections or accreditation processes to the VA Regional Commissioners.

(10) Ensures that all laboratory testing sites performing patient care testing meet requirements for hospital accreditation.

(11) Ensures that the facility submits to annual registration and FDA inspection if the facility draws or prepares components or provides transfusion services.

(12) Ensures that, if the P&LMS has a blood bank or transfusion service that meets any of the criteria as described in paragraph 7.b.(3) of this Handbook, that the blood bank/transfusion service undergoes and maintains current AABB inspection and accreditation.

(13) Provides oversight for ancillary testing sites. Ancillary testing encompasses or includes all laboratory testing sites that are outside of the physical limits or physical address of the main VA medical facility’s P&LMS. Additionally, ancillary testing includes all laboratory testing sites that fall under the auspices of the main parent facility even when they may be under a separate laboratory director, CLIA registration number, or separate accreditation. Point of care testing and HBHC, when such testing is performed by a VA employee or a contracted service employee in a patient’s home, is also included.

(a) Ensures that testing is in compliance with VA policies, and that good testing practices are utilized in all ancillary testing sites, including sites that fall outside of the accreditation umbrella of the main laboratory and are under the directorship of an individual other than the Chief or Director, P&LMS. A separate CLIA certificate is required for each separately-accredited test site. In such sites the Chief or Director, P&LMS is not directly responsible for results reported, but retains the responsibility of providing oversight and assistance to ensure that any testing performed is in compliance with 42 CFR Part 493 and existing VHA policies.

(b) Ensures that all laboratory testing performed, including testing performed by providers (e.g., physicians, dentists, nurse practitioners, midwives, clinical pharmacists, and physician assistants), is conducted under the oversight of the Chief or Director, P&LMS. The Chief or Director, P&LMS has a responsibility to ensure that the tests are being performed in accordance with 42 CFR Part 493 and existing VHA policy. In concert with the Chief of Staff, the Chief or Director, P&LMS must ensure that providers who fail to follow these testing requirements are not allowed to continue performing testing.

(c) Ensures that all laboratory testing performed by individuals without formal laboratory training is limited to those procedures classified as waived or moderate complexity level testing and is conducted under the oversight of the Chief or Director, P&LMS under the ancillary testing program.

(14) Acts as a consultant for the medical facility whenever a non-VA provider is contracted to perform laboratory testing for Veteran patients. The Chief or Director, P&LMS must ensure that documentation is obtained to verify that the contracted laboratory is appropriately CLIA certified.

(15) Selects and monitors all reference laboratories for quality of service.

(16) Assumes responsibility for the implementation of the quality management (QM) program and monitors the ongoing effectiveness of a comprehensive continuous QM plan. Ensures the QM program is conducted consistent with 38 U.S.C. 5705 and its implementing regulations.

(17) Ensures the QM program is assessed for continuous improvement and effective corrective and preventative actions on a regular basis.

(18) Ensures that test results are entered into the laboratory module of the Veterans Health Information Systems and Technology Architecture (VistA) or other VA designated management systems.

(19) Provides, for all ancillary testing sites, signatory support for legal medical interpretive reporting when the laboratory director of the ancillary testing site is a doctoral scientist. The VA medical facility's ancillary testing coordinator or other staff appointed by the Laboratory Director must provide QM oversight in each ancillary testing site.

(20) Encourages research; this may include externally-funded projects from national agencies such as VA, National Institutes of Health, American Cancer Society, etc.

(21) Manages data and trend analysis. All laboratories performing moderate or high complexity testing must participate in the VA Laboratory Management Information Program (LMIP), informational queries or surveys initiated by the National Director, P&LMS, or any other management information program designated as a VA national laboratory program.

(22) Provides the direction of professional aspects of post-mortem examinations.

(23) **Exception: The use of an Administrative Laboratory Chief with a Consulting Pathologist.** In a very small or remotely located VA medical facility, or in any VA medical facility where a pathologist cannot be successfully recruited, or there is not enough histology, cytopathology, or clinical pathology workload to justify a full-time or part-time pathologist in the laboratory, a board-certified, qualified, licensed consulting pathologist must be retained to fulfill the CLIA defined laboratory technical functions and an Administrative Laboratory Chief must be appointed. Before hiring a contracted consultant pathologist the following must be considered:

(a) Shared VA Chief or Director, P&LMS and Laboratory Director. Smaller VA laboratories within a VISN may choose to have a VA employed pathologist serve as the Chief or Director, P&LMS of more than one laboratory within the VISN or region. A qualified, licensed pathologist, board certified in anatomic pathology and/or clinical pathology by an American Board of Pathology employed by the VA may serve as the laboratory director for up to five non-waived laboratories. In such cases, local pathology groups may be contracted to perform laboratory technical functions and consultation as needed under the direction of the Chief or Director, P&LMS.

(b) Part-Time Pathologist Laboratory Director. Whenever possible, the VA should seek the employment of a part-time qualified, licensed pathologist, board certified in anatomic pathology and/or clinical pathology by an American Board of Pathology to serve as the laboratory director.

(c) Consulting Pathologist. When a part-time pathologist cannot be recruited, the facility may choose to enter into a contract for a pathologist's services. A contracted pathologist may not serve as the laboratory director or signer of the CLIA certificate, but may perform services under the direction of an Administrative Laboratory Chief.

(24) **Use of an Administrative Laboratory Chief.** When an Administrative Laboratory Chief is appointed, the following must be met:

(a) Serves as the laboratory director and therefore must meet the VA laboratory director qualifications for the appropriate laboratory complexity according to laboratory accreditation requirements, this Handbook (paragraph 6.c. and Appendix D), and as outlined in the laboratory director personnel standards in 42 CFR Part 493, Subpart M.

NOTE: CAP accredited laboratories with a total annual test volume exceeding 500,000 tests (including waived and moderate complex testing) must be directed by an individual who meets the high complexity laboratory director qualifications.

(b) Serves under the oversight of a VA pathologist who serves in the P&LMS service-line (e.g. aligned under a Chief or Director, P&LMS at a VA medical facility or under a pathologist service-line Chief or Director at the VISN level). Decisions on testing must be made by a pathologist in the P&LMS service-line.

(c) Ensures that, with the technical assistance of the consulting pathologist, the laboratory director responsibilities are discharged as cited in 42 CFR Part 493, Subpart M, and in accordance with laboratory accrediting organizations requirements, this Handbook, and VA regulations.

(d) Ensures all the responsibilities and functions outlined in paragraph 5.g. of this Handbook, Responsibilities of the Chief or Director, P&LMS, are met.

(25) Contracted Consulting Pathologist.

(a) A contracted consulting pathologist may not represent or obligate VA. The Administrative Laboratory Chief, a VA employee, must be the signer of the CLIA application.

(b) The consulting pathologist must be assigned as a member of the Clinical Executive Board or analogous medical staff committee, and all other appropriate committees.

(c) The consultant must actively participate in the educational and staff competency programs of the laboratory and of the institution.

(d) When the services of the pathologist are limited to those of consultant status, these services must be provided on a regular basis.

(e) A written report of the consulting pathologist's evaluation and recommendations must be provided with each visit.

(f) At each visit, the consultant must sign in and out in the Office of the Chief of Staff or Director of Clinical Services on official VA log sheets.

6. VA NATIONAL ENFORCEMENT PROGRAM CLIA APPLICATION PROCESS

a. **Scope.** All VA medical facility-based and stand-alone clinical laboratories or testing sites are required to register with the P&LMS National Enforcement Program to obtain a CLIA Certificate. This policy also applies to CBOCs that perform tests categorized as minimal complexity (waived) and/or PPM procedures and to any other VA testing site located at a unique address. Each testing site located at a separate address must apply for its own CLIA certificate. Laboratories within a VA medical facility that are located in contiguous buildings on the same campus and under common direction may file a single application for the lab sites within the same physical location

or street address. Sites meeting VA, federal regulations, and accreditation requirements for patient testing will be approved and issued a CLIA number.

(1) Each VA medical facility-based and independently accredited outpatient clinic laboratory must be issued a separate CLIA number.

(2) All ancillary testing sites under the accreditation umbrella of the main laboratory must be included under the main laboratory CLIA registration. Ancillary testing may include point of care testing, HBHC testing, testing performed at health fairs or stand-downs and, specialty laboratories.

b. CLIA Application Process.

(1) A CLIA application must be submitted and a CLIA Certificate or CLIA Application Letter of Acknowledgement from the National Enforcement Program must be obtained prior to the initiation of testing.

(2) When submitting an initial application for a new, non-waived testing site, the application for accreditation from a VA designated deemed status accrediting organization must be initiated within 30 days of beginning patient testing. A copy of the original accreditation application must be submitted to the Regional Commissioner's Office. The accreditation process must be completed within 1 year. A VA CLIA Certificate will not be issued until after accreditation has been achieved.

c. Laboratory Director Qualifications. Only a qualified, licensed pathologist, board certified in anatomic pathology and/or clinical pathology by the American Board of Pathology may serve as the laboratory director of a VA laboratory. Boarding should be consistent with the range of testing performed in the laboratory. The only exceptions are for ancillary testing sites when the Chief or Director, P&LMS already serves as the laboratory director of more than five non-waived labs or when a pathologist cannot be recruited to serve as the laboratory director. In such cases, the following requirements must be met:

(1) A non-pathologist physician may serve as the laboratory director for a CBOC laboratory or ancillary testing site which performs PPM or waived testing.

(2) A non-pathologist physician may serve as the laboratory director for a specialty laboratory, provided the physician has documented specialized training and/or experience specifically related to the specialized testing functions of the laboratory consistent with the requirements of 42 CFR Part 493, Subpart M and laboratory accreditation organizations. Testing performed in the specialty laboratory falls under the oversight responsibility of the Chief or Director, P&LMS. A non-pathologist physician may not serve as the laboratory director for a testing site that performs blood banking or anatomic pathology.

(3) In a very small or remotely located VA medical facility, in a VA medical facility where a pathologist cannot be successfully recruited, or there is not enough histology, cytopathology, or clinical pathology workload to justify a full-time or part-time pathologist

in the laboratory, a qualified non-pathologist physician may serve as the laboratory director (Administrative Laboratory Chief) provided the individual has documented specialized training and/or experience consistent with the requirements for the appropriate laboratory complexity according to laboratory accreditation requirements, this Handbook, and as outlined in the laboratory director personnel standards in 42 CFR Part 493, Subpart M. In such cases a board-certified, qualified, licensed consulting pathologist must be retained to fulfill the CLIA defined laboratory technical functions. In this situation, the Administrative Laboratory Chief will serve as the laboratory director and may perform the laboratory director functions, but must delegate the technical functions to the consulting pathologist. **NOTE:** *An Administrative Laboratory Chief must be aligned under the oversight of a VA pathologist who serves in the P&LMS service-line (e.g., aligned under a Chief or Director, P&LMS at a VA medical facility or under a pathologist service-line Chief or Director at the VISN level). Therefore, at the time of application, an organizational chart must be submitted with the CLIA application to define the alignment under the P&LMS service line.*

(4) An individual with a doctoral degree in biological science (doctoral scientist) may serve as the laboratory director for a CBOC laboratory, specialty laboratory, ancillary testing site, or a very small or remotely located VA medical facility (where a pathologist cannot be successfully recruited), performing waived and/or non-waived testing, provided the individual has documented specialized training and/or experience consistent with the requirements for the appropriate laboratory complexity according to laboratory accreditation requirements, this Handbook, and as outlined in the laboratory director personnel standards in 42 CFR Part 493, Subpart M. A doctoral scientist may not serve as the laboratory director for a testing site that performs blood banking, transfusion medicine, or anatomic pathology testing, except when the services of a consulting pathologist are retained. A doctoral scientist laboratory director must be aligned under the oversight of a VA pathologist who serves in the P&LMS service-line (e.g., aligned under a Chief or Director, P&LMS at a VA medical facility or under a pathologist service-line Chief or Director at the VISN level). Therefore at the time of application an organizational chart must be submitted with the CLIA application to define the alignment under the P&LMS service-line. A doctoral scientist may not serve as the laboratory director for a site that performs only PPM testing.

(5) The laboratory director must meet the laboratory director requirements for the appropriate complexity of testing as stated in 42 CFR 493 Subpart M and be qualified by virtue of documented training, expertise, and experience in the areas of analytical testing, and biological, chemical, or clinical science specially related to the testing site's testing functions. When laboratory testing is performed at testing sites (e.g., a CBOC or specialty laboratory) for which the Chief or Director, P&LMS is not the laboratory director (signer of the CLIA certificate), the Chief or Director, P&LMS provides oversight and assistance to ensure that testing is in compliance with VA policies and that good testing practices are utilized. The Chief or Director, P&LMS is not directly responsible for results reported.

(6) Each CLIA application for a non-pathologist to serve as the laboratory director of a waived or non-waived laboratory must be approved by the P&LMS Service-line

Director and the National Enforcement Officer. A non-pathologist lab director must be aligned under a Chief or Director, P&LMS service-line at a VA medical facility or VISN level. Therefore at the time of application an organizational chart must be submitted with the CLIA application to define the alignment under the P&LMS service-line.

d. **VA Laboratory Director Responsibilities.** The laboratory director must ensure that all laboratory testing performed under the CLIA certificate that is used for the diagnosis, treatment, and prevention of disease in patients must be provided in compliance with the requirements outlined in this Handbook and meet the regulations of 42 CFR Part 493 and CLIA.

(1) No individual may direct more than five laboratories that perform PPM, moderate or higher complexity testing as defined by CMS.

(2) When the laboratory director is located off-site from the laboratory, the laboratory director must perform onsite visits commensurate with the activities performed at the laboratory and of the frequency and duration required considered adequate by the laboratory and medical staff.

(a) For non-waived laboratories with very limited menus or performing only point of care testing, (except PPM laboratories), the laboratory director must visit the site at least once per year. This annual site visit cannot be delegated. Additional site visits may be delegated at the discretion of the laboratory director.

(b) For waived and PPM laboratories, the laboratory director may delegate site visits.

e. **CLIA Certificate.**

(1) VA facilities are required to revalidate their CLIA certificate with the P&LMS National Enforcement Program every 2 years.

(2) VA laboratories and testing sites issued a VA CLIA certificate are required to notify the Regional Commissioner of the following changes within 30 days of the occurrence:

(a) Laboratory name;

(b) Laboratory location or address;

(c) Director;

(d) Technical supervisor (laboratories performing high complexity only when the laboratory director is not qualified to serve as the technical supervisor);

(e) The addition of a specialty or subspecialty area that is not included on the laboratory's CLIA certificate; and

(f) The deletion of a specialty or subspecialty area that is included on the laboratory's CLIA certificate.

7. ACCREDITATION

a. **Scope.** All testing sites that perform laboratory tests for patient care within VHA must be in compliance with 42 CFR Part 493 and must maintain current accreditation by a nationally recognized, a VA designated accrediting agency. Testing sites are subject to inspection and accreditation and testing must be performed in compliance with any standards defined by the relevant accrediting organization.

b. **Accreditation Requirements.**

(1) All testing sites that perform tests categorized as moderate or high complexity (non-waived) for patient care must be accredited and inspected by a VA designated Laboratory Accreditation Program (LAP) of an accrediting agency with deemed status from the CMS. Reaccreditation inspections for these sites are required every 2 years.

(a) Primary accreditation and biennial inspection for all VA non-waived testing sites must be coordinated under a nationwide contract managed by the National Director, P&LMS.

1. The designated accrediting agency must have CMS deemed status.

2. Accreditation inspection teams of Medical Center Laboratories or laboratories performing anatomic pathology must include a pathologist inspector in order to provide peer review.

3. The laboratory specialties of histocompatibility, anatomic pathology, cytology, cytogenetics, molecular pathology, or other specialty designated by the National Director, P&LMS must be inspected by an individual with training and or working experience in that specialty area.

(b) All testing sites outside the physical limits of the main VA medical laboratory facilities or testing sites located in contiguous buildings or on the same campus as the main laboratory, including those performing Mohs surgery, testing in specialty laboratories, point of care testing, and testing performed in HBHC, at health fairs, or stand-downs are to be included as part of the main laboratory accrediting process, or must maintain a separate current accreditation by a VA designated, nationally recognized, CMS “deemed” accrediting body in compliance with CLIA, 42 CFR Part 493.

(c) CBOCs or other testing sites performing non-waived testing that are located at a separate address or campus cannot be included under the main laboratory’s accreditation process, but must undergo their own accreditation process.

(d) VHA research laboratories are not allowed to report laboratory results that are used for diagnosis, treatment, and prevention of disease in patients unless they are properly accredited and meet all requirements of 42 CFR Part 493.

(2) Sites that perform only tests categorized as waived or PPM testing performed by privileged providers may be inspected as a part of the main laboratory LAP or may be

accredited and inspected as a part of the main facility accrediting process. Reaccreditation inspections for these sites must be conducted as required by the respective accrediting agency. **NOTE:** *The PPM category of testing is exclusively for a select group of physicians and midlevel practitioners (dentists, nurse practitioners and midwives, and physician assistants) as defined in the CLIA regulations, 42 CFR 493.2) performing the test as part of a patient examination. If PPM procedures are performed by anyone other than this select group of providers, then the procedure is classified as moderate complexity level and those requirements apply.*

(a) The decision as to whether these testing sites should be included under the LAP or as part of the facility accreditation process must be made by the Chief or Director, P&LMS, in consultation with the medical staff and senior leadership within the individual facility.

(b) Should the organization choose to remove waived testing or PPM testing performed by privileged providers from under the jurisdiction of the laboratory accreditation umbrella, the Chief or Director, P&LMS, retains the responsibility to identify testing performed within the facility and to provide assistance and oversight to ensure that any testing performed is in compliance with 42 CFR Part 493 and existing VHA policies. In addition, a separate laboratory director for the waived or PPM testing must be identified on a separate CLIA certificate, which must be renewed every 2 years.

(3) The VHA requires that AABB standards for transfusion services and blood banks are adhered to as the single set of standards and to meet both AABB and the primary, VA designated, deemed status organization accreditation requirements. VA medical facilities are strongly encouraged to also apply for institutional membership in AABB, a nationally recognized professional organization which is actively engaged in improving blood banking through educational and accreditation programs. VA blood banks or transfusion services must seek and maintain current AABB accreditation if any of the following criteria are met:

(a) Dedicates six or more employee full-time equivalent (FTE) to the blood bank section.

(b) Provides specialized training for medical technology trainees in blood banking. This training is over and above the rotational training normally provided to all medical technology trainees.

(c) Draws autologous, directed, or allogeneic blood donors.

(d) Performs apheresis, therapeutic or non-therapeutic.

(e) Performs blood banking and/or transfusion medicine services for other VA medical facilities (does not apply to consolidations or mergers) or community institutions.

NOTE: *All VA laboratories must meet AABB requirements regardless whether or not they are AABB accredited.*

NOTE: AABB can coordinate joint accreditation inspections with the primary laboratory deemed status accreditation inspection if desired.

c. **FDA Registration.** Blood banks and transfusion centers are mandated to participate in the annual registration and FDA inspection if the facility draws or prepares components or provides transfusion services. **NOTE:** Reference for this action is *FDA-Compliance Program Guidance Manual – December 2010 Chapter 42 – Blood and Blood Products Inspection of Licensed and Unlicensed Blood Banks, Brokers, Reference Laboratories, and Contractors – 7342.001.*

d. **Enforcement Program Oversight.**

(1) On a periodic basis, accrediting and regulatory agencies summarize and submit the findings of their inspection and accreditation processes to the P&LMS National Enforcement Program, the VA Regional Commissioners, and to the individual facilities.

(2) If the accrediting organization reports problems having a potential for adverse patient outcomes and require corrective action, the P&LMS National Enforcement Officer will work with the Regional Commissioner, and the Chief or Director, P&LMS at the facility to ensure that corrective action is implemented in a timely manner.

8. PROFICIENCY TESTING

a. **Scope.** As an enhancement to the internal quality control program, to ensure reliability of patient testing in the laboratory, and to maintain accreditation requirements, all VA laboratories and ancillary testing sites that perform testing on patients must participate in external PT programs from a CLIA approved PT provider for all analytes for which PT is available, including waived testing, PPM, and unregulated analytes. All VA testing sites must maintain successful performance for all test methods and analytes.

b. **PT Requirements.** The laboratory must perform and report PT from a CMS approved provider or program approved by the VA National Enforcement Officer for every instrument/method (including backups) utilized for patient testing and for every site where patient testing is performed. All of these tests systems must be formally evaluated by the provider for satisfactory performance.

(1) A separate PT kit must be ordered for each instrument, method, or site utilized for patient testing. All the challenges provided in one kit for a specific analyte must be run on the same instrument, method, or site to allow the tracking of the instrument, method, or site performance throughout the year.

(2) Laboratories ordering multiple identical kits may not participate in any correlation or comparison of PT results prior to the submission cut-off. The specimens in each PT kit must be handled as unique specimens and run in the same manner as if different patient specimens had been provided in each PT kit.

(3) When analyte testing is performed on more than one instrument in the main laboratory and when testing is performed by employees under the direct supervisor of the laboratory director, PT may be performed on the primary instrument and a quality cross check survey may be performed each additional backup instrument/method to fulfill the PT requirement when a quality cross check survey is available from the VA specified PT contractor.

(4) Procurement of PT will be coordinated under the current nationwide contract managed by the National Director, P&LMS.

(5) If the laboratory chooses to purchase PT from a vendor other than the vendor(s) under VA contract, the laboratory must authorize the Proficiency Testing Program to release copies of all PT evaluation reports to the VA National Enforcement Program.

(6) For analytes that do not have formal PT available, an alternative method must be in place to assess the method accuracy at least twice a year (e.g., split samples analyzed in conjunction with another laboratory, or testing materials with assigned values as unknowns).

c. **Definitions.** The following definitions apply only to this paragraph 8.

(1) **Challenge.** A challenge is an unknown sample in a PT shipment. Usually one to five challenge(s) is (are) included for each analyte in each PT event.

(2) **Event.** An event is a shipment of a PT survey which is received two or more times per year and is usually comprised of one or more challenges for each analyte.

(3) **Transcription or Clerical Error.** A transcription or clerical error is when the PT result or other required information submitted to the PT provider is omitted or transcribed incorrectly. Transcription errors or clerical errors are counted as incorrect or unsatisfactory PT responses.

(4) **Regulated Analyte.** A regulated analyte is any analyte which has been defined as regulated in 42 CFR Part 493.

NOTE: *The laboratory is obligated to notify the PT provider of any PT provider-related error as soon as possible after receiving the evaluation report. Errors originating from the laboratory cannot be corrected once the report has been sent.*

d. **PT Evaluation.**

(1) **Evaluation Criteria.** CMS has determined analyte-specific evaluation criteria and target values that are used to grade each result for regulated analytes. In addition, CMS-approved PT providers may specify grading criteria for analytes other than those listed as CMS-regulated analytes. These allowable limits and target values are published with the peer group data in each participant summary that accompanies the laboratory's survey report. For regulated analytes; the allowable limits can be found in 42 CFR Part 493, Subpart I. VA laboratories must use the same grading criteria for the analytes that are formally evaluated.

(2) Evaluation Criteria for Analytes Not Formally Evaluated by the PT provider.

Some analytes and tests do not have defined grading criteria. Such quantitative challenges are graded as plus or minus 3 standard deviations (+/-3SD) or plus or minus 3 (+/- 3) standard deviation intervals (SDI) of the appropriate peer group mean. Tests for enzymes not formally evaluated are scored as +/- 20 percent of the peer group means. Qualitative challenges are graded against the intended response.

(3) If the formal or in-house PT results indicate a problem or are scored less than 100 percent correct, there must be an immediate investigation to determine the cause and corrective action taken, if necessary, to maintain reliable testing performance. A Corrective Action Plan consists of:

(a) A written narrative describing the laboratory investigation of the PT failure, including the conclusions as to the cause(s) of each unacceptable result;

(b) Specific actions taken to prevent reoccurrence; and

(c) Evidence that the problem has been corrected.

e. PT Scoring.

(1) To determine the score for the analyte testing event, the percent of acceptable analyte responses must be calculated as follows: (Number samples or analyte correct times 100) divided by Total number challenges or analyte.

(2) **Satisfactory PT Event.** A satisfactory PT event is a single PT event in which the total score for an analyte is within the limits described in the following:

(a) A score of 80 percent or greater for any analyte in an event which is composed of 5 samples.

(b) A score of 100 percent in blood group and type (ABO/Rh) or compatibility testing.

(c) A score of greater than 50 percent for any analyte in an event which is composed of less than five challenges.

(3) Unsatisfactory PT Event.

(a) Failure to attain a minimum satisfactory score on a single PT event described as follows:

1. A score of less than 80 percent for any analyte in an event which is composed of five challenges.

2. A score of less than 100 percent in ABO/Rh or compatibility testing.

3. A score of 50 percent or less for any analyte in an event which is composed of less than five challenges.

(b) Failure to participate in a PT event results in a score of zero for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if:

1. Patient testing was suspended during the time frame allotted for testing and reporting PT results;

2. The laboratory notifies the Regional Commissioner's Office within the time frame for submitting PT results of the suspension of patient testing and the circumstances associated with failure to perform tests on PT challenges; and

3. The laboratory participated in the previous two PT events.

(c) Failure to return PT results to the PT provider within the time frame specified by the program is unsatisfactory performance and also results in a score of zero for the testing event. **NOTE:** *The only exceptions may be for extraordinary circumstances or if the reason for the error is traceable to the PT provider.*

(d) An unsatisfactory testing event requires the laboratory to investigate the incident and, if possible, determine the problem and take appropriate corrective action. Documentation of the corrective action taken must be forwarded to the VA Regional Commissioner within 25 working days upon receipt of the PT evaluation report.

f. **PT Failure or Unsuccessful Participation.** PT Failure or unsuccessful participation is described as follows:

(1) A score of less than 80 percent on two out of three consecutive events for any analyte event which is composed of five challenges.

(2) A score of less than 100 percent on two out of three consecutive events in ABO/Rh or compatibility testing.

(3) A score of 50 percent or less on two out of three consecutive events for any analyte event which is composed of less than five challenges.

(4) A total (or overall) score of less than 80 percent on two out of three consecutive testing events for a specialty or subspecialty.

(5) A score of zero on two out of three consecutive events for failure to submit results to the PT provider within the specified timeframe.

g. **PT Failure Reinstatement Protocol.** In the event of a PT failure for any analyte, the laboratory is required to implement the following procedures:

(1) Cease testing for the particular analyte(s) on the suspect instrument. **NOTE:** *When analyte PT failure occurs on the primary instrument, any back-up method for that analyte on which a cross check survey has been performed in lieu of the regular PT program is also considered to be in failure and analyte testing must cease on the*

backup method/instrument(s). Backup instrument(s)/method(s) may be brought up to primary instrument status with the successful completion of a regular PT program.

(2) Immediately investigate the circumstances of the events that lead to the PT failure. The decision to resume testing is only to be made after the review of the information and approval by the Regional Commissioner. Notify (consult with) the Regional Commissioner's Office regarding the problem identified, the results of the investigation, and the corrective actions which have been implemented. The Regional Commissioner's Office determines, based on the preliminary investigation, any further actions that may need to be taken.

(3) The laboratory investigations performed must be thorough and include a review for:

- (a) Clerical errors;
- (b) Technical or methodological issues;
- (c) Problems with the PT material;
- (d) Quality control and maintenance records;
- (e) Policies and procedures;
- (f) Interviews with staff;
- (g) Performance on previous PT surveys; etc.

(4) The corrective action plan and supporting documentation must specifically address:

- (a) The details of the investigation;
 - (b) The retesting of the PT challenge(s), if possible;
 - (c) An evaluation of patient results at the time of the unsatisfactory PT performance;
 - (d) Any previous corrective action taken to prevent or minimize future recurrences;
- and
- (e) Any required staff education and training with documentation as to date, material covered, and persons attending.

(5) Arrange for two remedial testing events from a CMS-approved provider to be performed at the facility's expense and ensure that the results and the supporting data are sent to the VA Regional Commissioner. **NOTE:** *If at all possible, the same person who performed the previous unsatisfactory test(s) should run the remediation or reinstatement proficiency tests. Remedial testing must be performed on the instrument on which PT failure occurred.*

(6) If no CMS-approved PT provider exists for the failed analyte, the affected laboratory and the VA Regional Commissioner's Office determine the most effective and efficient way of reinstating testing (i.e., a split sample may be sent to the laboratory's usual reference laboratory). The results from the remedial PT/alternate testing must be sent to the VA Regional Commissioner's Office for review.

(7) When PT failure is attributed to the use of an incorrect method code or missing method code, the performance of a remedial PT event may not be required as per the discretion of the Regional Commissioner.

(8) The VA Regional Commissioner must review a copy of the laboratory's corrective action (see paragraph 8.g.) the results of the remedial testing, and supporting data. In addition, the Regional Commissioner may request additional corrective action, or the implementation of an additional training program as deemed appropriate. Testing may only resume when there is approval of the remedial testing and the laboratory's corrective action by the VA Regional Commissioner or the P&LMS National Enforcement Officer.

(9) Resumption of testing may only be authorized once the laboratory can verify to the Regional Commissioner that the following conditions have been met:

(a) There is no jeopardy to patient health and safety.

(b) The laboratory has provided the Regional Commissioner's Office with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful PT performance.

(c) The laboratory does not have a poor compliance history.

(10) The laboratory, as part of its Quality Management Program, must periodically reassess the implemented corrective action to ensure continued compliance to prevent the problem from reoccurring.

h. Should a laboratory have a PT failure on one instrument, but have successful PT performance on another instrument which performs the same test(s), it is only necessary to cease testing on the instrument or test system which had the PT failure.

NOTE: *When analyte PT failure occurs on the primary instrument and when a cross check survey has been used in lieu of the regular PT program survey on back-up method(s) for that analyte, both the primary and backup methods for that analyte are considered to be in failure.*

i. Should analyte failure occur only on a backup method/instrument cross check survey, then as part of the remediation the lab must convert to the performance of the regular PT program on that backup method.

NOTE: *See paragraphs 15.e., f., and i. for QM and PT requirements for anatomic pathology services.*

9. P&LMS NATIONAL ENFORCEMENT PROGRAM PROTOCOL

a. Scope.

(1) This paragraph provides direction and guidance to VA medical facilities regarding the enforcement of CLIA, as required by Pub. L. 102-139.

(2) All laboratories must maintain current accreditation by an approved nationally recognized organization and successfully participate in a CMS-approved PT program. Laboratories that perform clinical diagnostic tests on human specimens and fail to maintain current accreditation by a nationally-recognized organization according to the accreditation requirements as outlined in paragraph 7 of this Handbook status, or which fail to meet the PT requirements as described in 42 CFR Part 493, Subpart H, or who have demonstrated deficiencies which pose a direct threat to patients may be instructed to terminate those processes which are the basis of the failure.

b. VA P&LMS National Enforcement Program.

(1) The P&LMS National Enforcement Program is directly responsible for the effective management of the VA CLIA Program. The office becomes actively involved in communicating and initiating appropriate action to any situation in which a medical facility's accreditation is in jeopardy due to inspections or survey results, and/or complaints that impact public health, involve other government agencies, or has negative media coverage.

(2) The P&LMS National Enforcement Officer, with the assistance of the VA Regional Commissioners and Regional Technologists, is responsible for providing VA laboratories with the enforcement and oversight for compliance with federal regulations, this Handbook, and VA policies under the authority of the P&LMS National Enforcement Program. The VA Pathology Regional Commissioners and Regional Technologists support the National Enforcement Program by overseeing assigned regional area laboratory facilities to ensure appropriate accreditation and compliance with regulatory standards and directives.

c. VA Regional Commissioners. VA Regional Commissioners in concert with the Regional Technologists are responsible for:

(1) Providing laboratories with the assistance necessary to ensure accreditation by required reviewing organizations.

(2) Informing all testing sites of new standards and modifications to current standards of The Joint Commission, CAP, FDA, AABB, etc., and acting as a resource for questions concerning these standards.

(3) Ensuring that each P&LMS has a copy of VHA Handbooks and guidance documents dealing with laboratory inspection, accreditation requirements, and proficiency testing programs.

(4) Providing appropriate oversight of inspections.

(5) Analyzing inspection reports from all laboratories in their respective regions to identify serious problems and trends and reporting this information to the P&LMS National Enforcement Program Office and appropriate management officials.

(6) Initiating or participating in routine site visits, as well as conducting additional site visits that may be indicated when there is a reduction in the quality of laboratory performance.

(7) Providing consultation, as appropriate, for proposed corrective actions to correct deficiencies noted during inspections to ensure that the noted deficiencies or items of non-compliance have been completely corrected.

(8) Reviewing investigation reports from The Joint Commission, CAP, FDA, AABB, Office of the Inspector General, General Accountability Office, Medical Inspector dealing with P&LMS in their region, and following up with the laboratory in question to ensure that identified problems are corrected in a timely fashion.

(9) Advising the P&LMS National Enforcement Officer of problems and concerns relating to the quality of the work in P&LMS.

(10) Working with the National Enforcement Officer to ensure that all VA testing sites are in compliance with the inspection and accreditation requirements set forth by CMS-approved laboratory accrediting agencies elsewhere in this Handbook and VHA policies.

(11) Providing oversight of individual laboratory proficiency through the review and trending of PT results, tort claims, investigations, quality management activities, and external surveys.

d. **Enforcement Procedure.** In those instances where problems with the potential for adverse patient outcome are identified and require corrective action, the P&LMS National Enforcement Officer works with the VA Regional Commissioner, and the Chief or Director, P&LMS, at the facility to ensure that corrective action is implemented in a timely manner.

10. CATEGORIZATION OF SPECIFIC LABORATORY TEST SYSTEMS, ASSAYS, AND EXAMINATIONS BY COMPLEXITY

a. A laboratory test is defined as an examination, diagnostic, or monitoring procedure on a human specimen to determine specific information for diagnosis, treatment, or prevention of disease, and to detect the impairment of health status, or to assess the health of human beings.

b. CLIA and its implementing regulations categorize specific laboratory test systems, assays, and examinations by complexity (waived, PPM, moderate complexity, and high complexity). VA recognizes the complexity level for these laboratory procedures as listed in 42 CFR Part 493, but requires that certain minimal standards be met for performing and documenting these procedures.

c. Minimal testing guidance for all laboratory procedures within VHA is provided in paragraph 13.h. of this Handbook. In addition, all laboratory testing within VHA is subject to inspection and accreditation, and such testing must be performed in compliance with any standards defined by the relevant accrediting organization.

d. According to 42 CFR Part 493, tests that have not been categorized under the CLIA test complexity categorization provisions are considered to be high complexity. Any deviation from the manufacturer's guidance or VHA policy for performing the procedure must also result in the procedure being classified as high complexity.

11. TESTING PERSONNEL

a. Any individual performing laboratory testing which is used to determine specific information for diagnosis, treatment, or prevention of disease, and to detect the impairment of health status, or to assess the health of a human being for VA must meet the personnel requirements as defined in 42 CFR Part 493. This includes individuals performing testing outside the main laboratory such as testing performed at a health fair, stand down, point of care site, or other site where laboratory testing is performed. Furthermore, any individuals who perform laboratory procedures may only do so under the ancillary testing program and under the oversight of the Chief or Director, P&LMS.

b. CLIA regulations (42 CFR Part 493) allow more latitude in personnel requirements than regulatory agencies and the VA. The laboratory must follow the most restrictive guidelines when determining personnel qualification requirements. For assistance in determining qualification requirements, a chart is provided in Appendix D.

12. QUALITY MANAGEMENT PROGRAM (QM)

a. Scope.

(1) This paragraph defines the structure of QM programs for laboratory testing in all VA medical facilities, their outreach functions, and ancillary testing sites; and it applies to all sites that perform testing for the diagnosis, treatment, or prevention of disease in patients.

(2) The VA medical facility must provide an ongoing, comprehensive QM program under the direction of the Chief or Director, P&LMS, which:

(a) Evaluates the effectiveness of the laboratory and the medical center policies and procedures in providing the highest quality laboratory medicine test results and anatomic pathology reports.

(b) Ensures the availability of accurate, reliable, and timely laboratory medicine test results and anatomic pathology reports to the patient's health care provider.

(c) Documents all QM activities.

(3) The QM program must be defined in a written Quality Plan that provides a comprehensive, systematic approach that encompasses all sections of the laboratory

(clinical pathology, anatomic pathology, and ancillary testing) and defines the foundation elements or quality system essentials (QSE) of the quality management system. The quality management systems model and QSE outlined in the Clinical Laboratory Standards Institute (CLSI) document, *HS1, Quality Management System Model for Health Care*, is recommended. An example of a quality plan may be found on the P&LMS website: <http://vawww.lab.med.va.gov/>. **NOTE:** *This is an internal VA Web site that is not available to the public.*

(4) There must be an on-going, planned, systematic, and objective process for the monitoring and evaluation of the QM plan and the appropriateness of patient care provided by P&LMS.

NOTE: *Quality assurance/quality management activities generate confidential documents that may be protected as defined in 38 U.S.C. 5705 and its implementing regulations.*

b. **Required Elements for QM in Laboratory Services and Ancillary Testing Sites.** The Chief or Director, P&LMS, is directly responsible for ensuring that all laboratory testing performed within a VA facility, its outreach functions, and stand-alone outpatient clinics meets the QM requirements listed as follows:

(1) Appropriate written policies and procedures are in place for a comprehensive QM Program designed to monitor, evaluate, and improve the overall quality of the laboratory testing process in all testing sites in the medical center and its outreach functions, including ancillary testing and satellite outpatient laboratories. These policies must meet the requirements of the accrediting agencies.

(2) A system is in place to ensure that all complaints and problems reported to the laboratory are documented. Investigation of complaints and patient incident reports must be made and corrective action instituted, when indicated.

(3) There must be a process in place to review appropriateness of current test menus, requests for new tests, adequacy of referral testing laboratories, appropriateness of referral test requests (especially high cost tests), critical values, and point of care testing. The process implemented is at the discretion of Chief or Director, P&LMS, but may be accomplished by the development of a Medical Laboratory Advisory Group or other process.

(4) **Referral Testing.** There is an ongoing mechanism for monitoring and evaluating the usefulness and appropriateness of referral testing (i.e., that testing is sent to a CLIA-accredited laboratory) that the results obtained are of high quality, and that the test is appropriate for patient care.

(5) A system is in place to provide training and ongoing assessment of the competency of the individuals performing patient testing.

(6) In addition to regulatory and accreditation reporting requirements, all laboratory-related adverse events, fatalities, events considered “sentinel events” by The

Joint Commission, or blood product deviations must be reported to the appropriate VA Regional Commissioner.

c. Test Methods and Equipment Standards.

(1) Each Chief or Director, P&LMS, must establish standards and policies for the selection of tests, validation and implementation of analytical systems, and test methods.

(2) For all FDA-approved analytical systems and test methods, including waived tests, a system must be in place to ensure that all test methods are validated prior to the implementation. The validation protocol is at the discretion of the Laboratory Director, but at a minimum must meet the manufacturer's recommendations, accreditation requirements, and be consistent with the requirements outlined in 42 CFR 493.1253, as applicable.

(d) Initial correlation studies must be performed between the new test or method and current instruments or methods providing results for the same analyte.

(e) Quality control is validated in accordance with current accepted scientific guidelines or accrediting agency requirements. When alternative quality control is utilized, it must be implemented using the concepts of laboratory quality control-based risk management.

(3) For non-FDA-approved, laboratory modified FDA-approved methods, or tests developed in-house, the laboratory must perform an extensive study to establish and document the method's performance specifications. Protocols using CLSI guidelines are recommended. For in-house developed methods or systems, the frequency of calibration depends upon the scientific data to ensure that reliable testing is provided by the laboratory.

(4) All test methods and instruments must have clearly written manuals available in each testing area to substantially comply with current laboratory accreditation requirements.

(5) The laboratory must, as a minimum, follow the manufacturer's recommendations for performing the testing including, but not limited to: quality control, reagent storage, maintenance, function checks, etc. When the manufacturer does not specify quality control requirements, the laboratory must assess the testing process and implement a quality control (QC) plan based on risk assessment. The risk assessment process found in CLSI document, *EP23-A, Laboratory Quality Control Based on Risk Management*, is recommended.

(6) New lots of reagents must be validated for all tests including waived testing.

(7) If tests are performed using different methodologies, instruments, or at other testing sites within the VA medical facility, the Chief or Director, P&LMS must ensure

that correlation studies between the main laboratory and these other test sites are performed at least twice yearly.

(a) For waived tests, patient correlations need only be performed on a rotating subset of instruments twice yearly.

(b) The Laboratory Director determines the size of the subsets.

(8) Whenever possible, the analytical systems must be interfaceable with the VA medical facility's VistA computer system.

d. **Patient Test Management.** The Chief or Director, P&LMS must ensure that, for all testing sites within and affiliated with each VA medical facility that perform laboratory tests on patients for diagnosis, monitoring therapy, or the progress of disease that:

(1) Standards, procedures, and policies are developed for reporting of timely, accurate, reliable and clear test results.

(a) Policies for detection of potential errors or differences in test results for the same analyte between the clinical laboratory and all ancillary testing sites in the VA medical facility are established.

(b) There is a process to ensure all laboratory test results are reviewed for accuracy of reporting by testing personnel or verified with a validated auto-verification process that compares results against laboratory-defined acceptance parameters before the data is released to the health care providers.

(c) All laboratory test results, both clinical and anatomic pathology, in which there is a previously undiagnosed cancer or malignancy (excluding skin squamous and basal cell carcinomas) must be communicated verbally to the patient's provider as soon as possible (ideally, within 1 working day of the time that diagnosis was made). In addition to anatomic pathology findings, this would include cancers or malignancies identified in definitive testing in clinical hematology or molecular pathology. These communications must be documented in the specimen report by the pathologist who notifies the patient's provider.

(d) All laboratory tests, regardless of where they are performed, will have the results entered into the laboratory module of the patient's electronic medical record. This includes all tests performed on VA patients by non-VA laboratories where specimens or test results are processed through P&LMS and where testing has been ordered by a VA provider or contract provider for use in providing patient care. This would not apply to testing that is ordered by a non-VA provider and used by a VA provider to treat or monitor a VA patient, as might be the case for shared or co-managed patients. In that case, the results and all appropriate information (e.g., reference range, name of testing laboratory, etc.) should be included in a progress note or included in the paper medical record or scanned into the patient's electronic medical record. This would also not apply to patient self-generated results. Patient self-generated or self-test results may

be entered elsewhere in the patient's electronic medical record, but will not be included in the laboratory test file.

1. Only laboratory results that are ordered by a VA provider and tested by a VA laboratory, VA contracted laboratory, or agent of the VA laboratory should be entered into the laboratory module of VistA or approved laboratory software.

2. PPM or testing performed as part of the patient exam may be entered in the provider's notes.

3. For referral testing in which the results are complex with long narratives, a copy of the referral report may be entered into VistA imaging, provided the test is accessioned in VistA and the location of the imaged document is entered in the comment of the VistA results so the test result can be located.

4. In the case of testing that is ordered by a non-VA provider and used by a VA provider to treat or monitor a VA patient, as might be the case for shared or co-managed patients, the results and all appropriate information (e.g., reference range, name of testing laboratory, etc.) must be included in a progress note, paper medical record, or scanned into the patient's electronic medical record as a note.

(2) If an error is found on a released-patient result, the appropriate designee must communicate immediately with the health care provider in charge of the patient and document the communication. The Chief or Director, P&LMS, or designee, must ensure that the report is corrected in the VistA computer system. Both original and corrected results automatically become part of the data released to the health care providers, to the wards, and will become part of the patient's permanent record.

(3) Clearly written policies and procedures are developed to:

(a) Review processes for electronic data transmission. For example, programs must be developed so that the VistA computer system checks the entered data against predefined limits established by the Chief or Director, P&LMS, for such tests that are identified and flagged with high, low, and critical values. Entries or results outside of the predefined limits will not be accepted.

1. Display previous patient test results with a delta check.

2. Identify all significant abnormalities by an audible "beep" and a visual "flag" observed next to the test values.

(b) Ensure correction of detected errors and documentation of correction.

(c) Ensure correct patient identification.

1. The testing site must have written policies which ensure the positive identification of the patient and all patient specimens, from the time the specimen is collected until testing has been completed and the results reported.

2. In addition to ensuring the positive identification of specimens, the testing site must ensure optimum integrity of the specimens from the time of collection until testing has been completed and the results reported.

e. **Specimen Identification for Employee Random Drug Testing.** If specimens are collected for random drug testing, the Chief or Director, P&LMS, must ensure that a written specimen collection and identification policy is in place. The laboratory must follow Federal regulations for collection and specimen management. This policy must include:

- (1) Standards on specimen requirements;
- (2) Validity of specimen and person;
- (3) Chain of custody;
- (4) Security of specimen; and
- (5) Preservation of confidentiality of the individual and the individual test results.

f. **Retention of Specimens, Slides, and Records.**

(1) Records must be retained in accordance with the requirements of VHA Records Control Schedule 10-1, Section VIII- Laboratory Service (113), CLIA, AABB, CAP, TJC, or other deemed status accrediting organization, whichever is the most stringent.

(2) Slides, specimens, and tissue must be retained in accordance with the requirements of the VHA P&LMS Retention Requirements (located on the P&LMS website at: http://vawww.lab.med.va.gov/References_Directives_and_Regulations.asp, CLIA, AABB, CAP, The Joint Commission, or other deemed status accrediting organization, whichever is the most stringent. **NOTE:** *This is an internal VA Web site that is not available to the public.*

g. **Discontinuation or Merger of Anatomical Pathology Services.** When anatomical pathology services at a VA facility are discontinued or merged with another VA facility, all documentation and specimens required to be maintained must be transferred to the VA facility where the scope of services for the patients of that facility have been transferred.

13. ANCILLARY TESTING

a. **Scope.**

(1) This paragraph provides direction and guidance to VA medical facilities regarding ancillary testing. Ancillary testing is defined as laboratory testing or services performed within a VA medical facility or its outreach functions but outside the physical facilities of the main clinical laboratory. This includes testing performed by a VA employee or a contracted service employee in a patient's home under the program or testing done as point of care at bedside.

(a) Ancillary testing includes, but is not limited to:

1. Waived, PPM, and non-waived testing performed outside of the physical limits of the main VA P&LMS.

2. Testing performed by non-laboratory personnel, including physicians and other providers.

(b) Ancillary testing encompasses:

1. Point of care testing;

2. Testing within the health care system that is under a separate laboratory director, separate CLIA registration number, or separate accreditation;

3. Testing performed in a laboratory or testing site outside the physical limits of the main laboratory that is under the accreditation umbrella of the main laboratory; and

4. HBHC when testing is performed by a VA employee.

(2) All ancillary testing sites are required to be under the oversight of the Chief or Director, P&LMS, and inspected and fully accredited by an appropriate, VA-designated accrediting body.

(a) An ancillary testing coordinator generally monitors and oversees the ancillary testing sites for the Chief or Director, P&LMS.

(b) For ancillary testing sites that are not under the direct oversight of the Chief or Director, P&LMS, such as testing sites in which the Chief or Director, P&LMS is not the laboratory director, the Chief or Director, P&LMS remains responsible for ensuring that the testing is carried out in accordance with 42 CFR Part 493 and VHA policy, but is not responsible for the test results.

(c) The senior leadership, in consultation with the Chief or Director, P&LMS, decides on the type of inspection and accreditation those sites offering waived and PPM procedures will undergo.

(d) All other testing within the facility that falls under the main laboratory's accreditation umbrella must be inspected during the main laboratory's biennial inspection by the VA designated laboratory accrediting agency.

b. Responsibilities.

(1) The Chief or Director, P&LMS, in concert with the Chief of Staff or Director of Clinical Services, identifies the location and type of all ancillary laboratory testing performed within the health care system, including point of care testing, PPM testing, HBHC testing, testing performed in satellite laboratories, and testing performed for patient care in research laboratories.

(2) The Chief or Director, P&LMS decides, in consultation with the medical and nursing staff, which tests may be performed outside the main clinical laboratory for patient care diagnostic or monitoring purposes, and the equipment needed.

(3) Quality management records for all VA ancillary testing sites must be reviewed by the Chief or Director, P&LMS or designee.

(4) The Chief or Director, P&LMS must appoint an ancillary testing coordinator to provide oversight for ancillary testing within the health care system.

c. **Ancillary Testing Coordinator.** The ancillary testing coordinator, or the individual responsible for the laboratory portion of the ancillary testing program, must be a fully qualified, certified medical technologist with experience in appropriate areas of laboratory testing. This individual:

(1) Provides technical oversight for all ancillary testing sites.

(2) Participates in the selection of methodologies appropriate for the clinical use of the test results.

(3) Participates in the validation of methods and test procedures performed and the establishment of the test performance characteristics.

(4) Participates in the planning, design, implementation, and assessment for all elements of the ancillary testing quality management program.

(5) Ensures that training and competency assessment for all persons who perform ancillary testing is completed and that employee records are complete.

(6) Ensures enrollment and participation in a proficiency program for all ancillary sites commensurate with the testing services offered, and oversees necessary remedial action when necessary.

d. **Test Results.** The results of all ancillary testing must be entered into the official VA laboratory computer package. Privileged providers performing waived or PPM testing as a part of their routine exam may enter testing results in the progress notes. The VA minimal testing requirements for documentation must be met (see paragraph 13.h.).

e. **Ancillary Testing Devices.**

(1) Laboratory testing by ancillary testing devices must, at a minimum, be conducted according to the manufacturer's standard operating procedures, including calibration and maintenance procedures, accreditation requirements, and VA minimal testing requirements.

(2) Routine maintenance and cleaning must be performed as specified by the manufacturer. Point of care instruments must be cleaned according to VA reusable medical equipment (RME) protocols.

(3) Correlation studies must be performed for those tests performed by different methods or on different instruments.

(a) For those tests performed by different methods or on different instruments within the medical center, correlation studies must be performed twice per year.

(b) For waived tests, patient correlations need only be performed on a rotating subset of instruments twice yearly.

(c) For testing sites located on a different campus or address but within the same healthcare system, correlations must be performed between the main medical center laboratory and the remote testing site to define relationship between test methods prior to the implementation of new tests or methodologies.

f. **Patient Self-testing**

(1) Patients may not perform self-testing within a VA medical facility or VA clinic except when self-testing is required as part of a patient education program or the patient is in a domiciliary or similar situation and adjusting their own medication.

(a) The Chief or Director, P&LMS is responsible for ensuring that all laboratory testing performed within the VA medical facility or clinics is compliant with regulatory requirements and, therefore the Chief or Director, P&LMS has jurisdiction over policy decisions for testing performed in that professional setting.

(b) Patient self-testing management does not fall under the responsibilities of the Ancillary Testing Coordinator. Patient self-testing must be managed under the facility self-testing program.

(2) The decision as to whether providers may treat a patient based on the patient's home testing results is not a laboratory decision, but must be made by the medical center leadership in compliance with local policy VA National Policies, and in collaboration with the self-testing program manager.

(3) The Chief or Director, P&LMS or designee must collaborate and provide consultation to the service managing the patient self-testing program when a patient self-testing program is implemented including:

(a) Test selection; P&LMS ensures the test selection is appropriate for the intended use;

(b) Device selection; P&LMS ensures the selected device meets VA and regulatory requirements;

(c) Development of protocols for test method validation; P&LMS serves as a subject matter expert for validation;

(d) Development of test protocols; P&LMS serves as a consultant as needed; and

(e) Implementation of training programs for staff and patients on the operation, maintenance and cleaning of self-testing devices.

(4) Accreditation requirements specify that only laboratory results performed under a CLIA certificate and performed at an appropriately accredited laboratory may be entered into the laboratory database. Therefore, results of patient self-testing may never be entered into the P&LMS package of the patient medical record. Results of patient self-testing may be entered elsewhere in the patient's electronic record, separate from the P&LMS data, according to the protocols set forth by the service responsible for the patient self-testing program.

g. **HBHC Testing.** When testing is performed by a VA employee or a contracted service employee in a patient's home under the HBHC Program, the testing is considered ancillary testing and all standards apply.

h. **Privileged Provider Minimal Testing Standards.** The following minimal standards must be met for all laboratory testing, including waived and PPM procedures, regardless as to whether or not the Chief or Director, P&LMS is the designated laboratory director on the CLIA certificate for that testing site. While the Chief or Director, P&LMS, in some instances may not be directly responsible for the laboratory results released by these providers, the Chief or Director, P&LMS, must be involved in selecting test methods that are appropriate for use by the providers and must ensure that there is a mechanism in place that validates compliance with required testing standards and VHA policy. The recommended mechanism to achieve this outcome is to provide oversight and monitor all such testing under the ancillary testing program.

(1) Personnel performing these procedures are expected to follow good laboratory practices in terms of quality control, quality assurance, and PT.

(2) The procedure must be performed strictly in accordance with the manufacturer's instructions.

(3) Written policies and procedures must be in place for performing the test.

(4) Patient test results must be documented in the patient's medical record. For qualitative results of patient tests performed by privileged providers as part of the patient exam (such as occult blood or PPM tests), the patient test results and the date the test was performed may be documented in a progress note in the patient's record. All other results (qualitative or quantitative) require entry into laboratory module of the VHA computer system.

(5) Quality control lot numbers and results must be documented for review and trending purposes using manual logs or computer-based programs. For non-instrument based waived or PPM patient tests performed by privileged providers (such as occult blood tests), the quality control results may be documented in the patient chart or in separate logs. The quality control lot number used for the patient testing must also be documented.

(6) All test sites must enroll in a formal PT program according to the VA requirements, when one is available. When a formal PT program is not available, the organization must have a system in place that verifies, at least twice a year, the accuracy of test results.

(7) A system must be in place to provide ongoing assessment of the competency of the individuals performing patient testing.

(8) All laboratory testing must be carried out in accordance with applicable accreditation standards.

(9) When testing is performed at more than one site within the organization, correlation testing must be performed between the testing sites at least twice per year. Correlation testing must be performed between the main laboratory and ancillary testing sites as described in paragraph 13.e.(3) of this Handbook.

(10) When a new test methodology is implemented, the organization must perform and document method validation for all testing complexities, including waived testing, consistent with the requirements listed in 42 CFR 493.1253.

14. IMMUNOHEMATOLOGY, BLOOD TRANSFUSIONS, AND TRANSFUSION MEDICINE TESTING

a. **Scope.** VA must provide suitable blood, blood components, fractions, and derivatives to meet the transfusion needs of patients under treatment in VA medical facilities. The term “blood” used in this paragraph includes blood, blood components, and coagulation derivatives. **NOTE:** *The term “blood” does not include albumin or other derivatives.*

(1) Only blood from volunteer donors can be utilized.

(2) The transfusion service must have emergency operation policies, procedures, and processes to ensure continued operation of essential functions in the event of an emergency or a disaster.

(3) **Contracted Transfusion Services.** Sites that contract all pre-transfusion testing services and perform only blood storage, issue blood products, and transfuse blood products on site must also meet applicable requirements outlined in this Handbook, VHA policies, and accreditation requirements.

(a) The transfusing site must have written policies clearly defining the responsibilities for the transfusion process.

(b) The transfusion site must register with the FDA.

(c) All blood products must be logged into VistA Blood Establishment Computer System (VBECS). Blood products must be issued in VBECS in real time in order to fully utilize the VBECS safety functions.

(d) There must be written policies and procedures for all aspects of the transfusion process as outlined by VA and accreditation requirements. (e.g., specimen procurement, the storage of blood products, issuing of blood products, the transfusion process, response to transfusion reactions, etc.)

(e) Staff responsible for issuing and storing blood must undergo initial training and annual competency assessment, commensurate with their activities.

(f) Transfusion staff must undergo training and competency in the transfusion process and recognition of transfusion reactions.

(g) There must be a process in place to perform Blood Utilization Review consistent with VHA Directives and policies.

(4) The use of autologous donation is not generally recommended. However, a means must be provided for patients to undergo autologous pre-operative donation when deemed appropriate, whether at the VA medical facility or at a blood center supplying other blood components to the VA medical facility. The patient's provider is responsible for ensuring patient safety and advising against autologous donation if physical risks to the patient are evident.

(5) The available evidence suggests that blood from directed donors is less safe than that from volunteer community donors. Furthermore, there is an increased administrative cost associated with this procedure. As a result, directed donation is not generally recommended.

(6) Transfusion practices and problems must be reviewed regularly and documented in the minutes of the Blood Utilization Review/Transfusion Utilization Committee. Clinicians must participate in the peer review process.

(7) The medical facility must exercise "blood management principals" to ensure the safe and efficient use of the many scarce resources involved in the complex process of expensive blood component therapy. The medical facility will move towards initiating a "Patient Blood Management Program" that implements evidence-based transfusion guidelines to reduce variability in transfusion practice and must engage multidisciplinary healthcare teams to study, implement, and monitor local blood management strategies.

(8) Blood bank or transfusion services must use the blood bank module software of the laboratory package of VBECS or any future authorized replacement for all blood bank or transfusion practices in place at the facility or outreach clinics. Local modifications to the VA blood bank software are strictly prohibited.

(9) VA blood bank modules must be used as the activity occurs, as designed, in order to take full advantage of the safety features.

(10) There must be records that allow for the traceable identification of the blood or blood component donor and the recipient and vice-versa in the event of a transfusion

problem such as a transfusion reaction, recall, withdrawal, or a look-back from the recipient.

(11) Blood Transfusion Record Form (BTRF), VA Standard Form (SF) 518, Blood or Blood Component Transfusion Form, or authorized equivalent must be used for the documentation of the transfusion. **NOTE:** *This also applies to contracted blood bank services.*

b. Inspection, Accreditation, and Standards.

(1) Each VA blood bank or transfusion service is mandated to register with the FDA.

(a) The reference for this action is FDA-Compliance Program Guidance Manual – December 2010 Chapter 42 – Blood and Blood Products Inspection of Licensed and Unlicensed Blood Banks, Brokers, Reference Laboratories, and Contractors – 7342.001 Appendix J.

(b) Non-compliance issues cited on FDA inspection must be addressed and corrected.

(2) VA medical facilities are strongly encouraged to apply for institutional membership in AABB, a nationally-recognized professional organization actively engaged in improving blood banking through educational and accreditation programs.

(3) If the laboratory meets the criteria listed in paragraph 7.b.(3), then AABB accreditation is required.

(4) As AABB standards are considered the industry standards, VA blood bank or transfusion services must meet these standards regardless of whether or not they are AABB accredited.

c. Blood Bank Transfusion Service QM Requirements.

(1) Each VA medical facility must have Blood Utilization Review/Transfusion Utilization Committee. **NOTE:** *The review process must be conducted consistent with 38 U.S.C. 5705 and its implementing regulations.*

(a) The appointed Blood Utilization Review Committee/Transfusion Utilization Committee Chair must be a physician with knowledge and experience in transfusion medicine. The Blood Utilization Review Committee/Transfusion Utilization Committee Chair is responsible for oversight of the blood usage review.

(b) Each VA medical facility must have a written Blood Utilization Review/Transfusion Utilization Policy.

(c) The Blood Utilization Review Committee/Transfusion Utilization Committee must be composed of multidisciplinary members knowledgeable and experienced in one or more aspects of transfusion therapy and blood banking.

(2) The Blood Bank Transfusion Service must have an ongoing mechanism for monitoring and evaluating those aspects of care that are most important to the health and safety of the patient, including the incidence of various types of transfusion reactions.

(3) All hemolytic and other life-threatening transfusion reactions must be reported through the VA medical facility's Patient Incident Reporting Program.

(4) Reports of Incidents and Adverse Events.

(a) Events considered "sentinel events" by The Joint Commission must be reported to the appropriate VA Regional Commissioner. VA Regional Commissioners are then responsible for expediently reporting the incident to the P&LMS National Enforcement Officer.

(b) All transfusion associated fatalities and biological product deviations (BPD) must be reported directly to FDA consistent with the requirements of 38 U.S.C. 5705 and a copy forwarded to the appropriate VA Regional Commissioner. VA Regional Commissioners are then responsible for expediently reporting the incident to the P&LMS National Enforcement Officer.

(c) Reports of incidents and adverse events are confidential documents that may be protected as defined in 38 U.S.C. 5705 and its implementing regulations. When such reports lead to a performance review or a Board of Investigation, the report retains confidential status even though documents resulting from the performance review or Board of Investigation are not confidential.

(5) **Blood Bank or Transfusion Service Quality Plan.** Each blood bank or transfusion service must develop and maintain a Quality Plan that meets the requirements of regulatory or accreditation agencies. The Quality Plan must address each of the following:

- (a) Organization;
- (b) Resources;
- (c) Equipment;
- (d) Supplier and customer issues;
- (e) Process control;
- (f) Documents and records;
- (g) Deviations, non-conformances, and Adverse Events;
- (h) Internal and External Assessments;
- (i) Process improvement through corrective and preventive action;

(j) Service; and

(k) Policies regarding facility issues (space, environment, etc.) and safety.

NOTE: An example of a written quality plan consistent with AABB requirements may be found on the P&LMS website: <http://vawww.lab.med.va.gov/>. **NOTE:** This is an internal VA Web site that is not available to the public.

d. Operation of Homologous (Allogeneic) and Autologous Blood Donor Program(s).

(1) If blood or other blood components (whole blood, platelets, bone marrow, etc.) are collected from blood donors (homologous and autologous), all policies and procedures must meet the requirements of the current FDA good manufacturing procedures (GMPs) and the current edition of the AABB Standards for Blood Banks and Transfusion Services, regardless of the number of donors to be collected on an annual basis.

(2) All prospective donors must be informed that required transfusion transmitted disease marker testing will be performed. The donor must sign an informed consent for performance of this required testing.

(3) Donors must be provided the opportunity to indicate in confidence, at the time of donation, that blood collected may be unsuitable for transfusion. One mechanism is known as Confidential Unit Exclusion (CUE), which allows the donor to indicate that the unit of blood should not be used for subsequent transfusion.

(4) Facilities that perform automated apheresis procedures for the purposes of collecting and preparing blood components must have the medical and technical expertise to perform this procedure.

(a) A unique informed consent is required for automated apheresis and donor procedures, the donor must be apprised of all relevant aspects of the procedure in advance.

(b) A physician must be on the premises and immediately accessible to handle adverse reactions to automated apheresis and blood collection procedures.

(5) Testing for markers of transfusion transmitted disease can be performed at another VA medical facility or at an outside laboratory, providing that laboratory holds a current certification of accreditation under CLIA.

(6) Donors must be notified of positive disease marker test results by the responsible physician and offered counseling. When the appropriate release of information consent form has been received, results of disease marker testing are to be forwarded to the donor's designated physician.

e. Special Procedures.

(1) Directed Blood Donations.

(a) If, after consultation with the patient's provider and the blood bank or transfusion service staff, it is determined that directed donations are the only course of action for meeting the transfusion needs of that patient, such units may be drawn or requested from an accredited blood supplier.

(b) The patient's provider is responsible for explaining to the patient that not all volunteers may be acceptable donors and the risks involved in the event that the patient's blood need exceeds the number of directed units available, requiring supplementation of allogeneic units from stock.

(2) Therapeutic Phlebotomy.

(a) Therapeutic phlebotomy may be performed only when ordered by physician.

(b) When therapeutic phlebotomy procedures are conducted within the medical center, but not provided under the services of the laboratory, the laboratory is to provide guidance to the service performing the procedure and must ensure that the procedure is performed consistent with AABB standards.

(3) Therapeutic Apheresis.

(a) Facilities that perform therapeutic apheresis must have the medical and technical expertise to perform this procedure.

(b) Therapeutic apheresis procedures may be performed only when ordered by the physician.

(c) A unique informed consent is required for apheresis procedures; the patient must be apprised of all relevant aspects of the procedure in advance.

(d) A physician must be on the premises and immediately accessible to handle adverse reactions to apheresis.

(e) When therapeutic apheresis procedures are conducted within the medical center, but not under the auspices of the laboratory or by contracted services, the Transfusion Service Medical Director or the Chief or Director, P&LMS must provide guidance to the service performing the procedure to ensure that the procedures are performed consistent with AABB standards.

(4) Perioperative Autologous Procedures.

(a) For laboratories that have assumed responsibility of the perioperative autologous or blood salvage procedures performed during surgery, the program must comply with AABB standards.

(b) When perioperative autologous procedures are conducted within the medical center, but not under the auspices of the laboratory or by contracted services, the

Transfusion Service Medical Director or the Chief or Director, P&LMS must provide guidance to the service performing the procedure to ensure that the procedures are performed consistent with AABB standards.

(5) Human Cells, Tissue, and Cellular or Tissue-Based Products (HCT/Ps).

(a) For laboratories that have accepted responsibility for the acquisition and storage of HCT/Ps, the products must be acquired from manufacturers that meet applicable VA standards and that are registered with the FDA.

(b) Blood banks and tissue banks must establish mechanisms to capture traceability of the product from acquisition to storage, distribution, and final disposition. Standard operating policies and procedures must adhere to the facility accrediting agency requirements.

(c) Laboratories that have accepted responsibility for the acquisition and storage of HCT/Ps must be accredited for tissue banking. It is strongly recommend that these sites undergo AABB tissue banking accreditation.

f. Transfusion Complications.

(1) General Principles.

(a) All suspected transfusion reactions occurring in medical centers for which VA has investigational responsibility, including home transfusions or transfusions in extended care centers, must be promptly investigated by blood bank or transfusion service personnel.

(b) If suspected complications occur during a transfusion, the transfusion must be interrupted and the patient's provider and blood bank or transfusion service notified immediately. The transfusion may be resumed only with appropriate medical approval, once it has been determined to be safe to resume.

(c) The VA medical facility must promptly (e.g., no longer than 8 hours following report of the event) investigate all transfusion reactions in accordance with the facility's established procedures. The extent of the investigation is determined by the Transfusion Service Medical Director and the Chief or Director, P&LMS, or designee.

(d) Transfusion Service Medical Director or designee must record in the patient's medical record a report and evaluation of the transfusion reaction in accordance with the facility's established procedures.

(e) All necessary remedial actions taken to prevent recurrences of transfusion reactions must be documented in the VA medical facility blood bank and in the minutes of the VA medical facility multidisciplinary committee responsible for oversight of the blood bank or transfusion service.

(2) Transfusion-Transmitted Diseases.

(a) Suspected incidents of transfusion-transmitted diseases must be investigated to determine if the etiology can be traced to a blood or blood component transfusion.

(b) When a patient receives unsuitable blood, blood product, or HCT/Ps, the recipient's provider is responsible for notifying the patient. The provider must document this notification and the notification must be maintained in the chart and a copy maintained in the blood bank or transfusion service.

(c) The procedures for look-back and notification must follow those listed in 21 CFR 610.47.

g. Computer Requirements for Blood or Blood Component Transfusion.

(1) Responsibilities.

(a) VA developers or commercial vendors of laboratory software are responsible for:

1. Identifying potential control functions;
2. Providing a listing of error and warning messages;
3. Informing the user of override capabilities;
4. Detailing information regarding design specifications and testing prior to release;
5. Developing sample test plans and worksheets for use in validation; and
6. Providing user manuals, user training, and customer support.

(b) The VA medical facility Director, or designee, is responsible for ensuring that Information Technology (IT) staff provide the following:

1. Resources to IT for appropriate operator support;
2. Appropriate hardware; and
3. Appropriate backup procedures for computer downtime.

(c) IT is responsible for installing the released version of the software. **NOTE:** Local modifications to the VA blood bank software are strictly prohibited.

(d) The Chief or Director, P&LMS, or designee, in conjunction with the Transfusion Medical Director, is responsible for:

1. Approval of overall functionality;
2. Review of the validation testing results; and
3. Collaboration with IT, as appropriate.

(e) The blood bank supervisor, in conjunction with the laboratory computer application coordinator(s), is responsible for:

1. Ensuring appropriate procedures are in place, including a validation test plan;
2. Maintaining required documentation;
3. Ensuring adequate training of personnel;
4. Identifying control functions for options and routines used at that medical center;
5. Understanding the documentation provided by the vendor; and
6. Assessing the spectrum of control for the control functions.

(f) The blood bank staff is responsible for referring to and following established procedures in the procedure manual(s) and maintaining appropriate information security according to VA and Federal government policy and procedure.

(2) Minimum Standard Operating Procedures for the Computer Functions.

(a) The standard operating procedures (SOP) must contain information on how the computer functions are integrated into the daily operation, reflecting the current version of the laboratory software.

(b) A written contingency plan must exist which details the SOP and a backup system to be used during computer downtimes. The ability to immediately activate this plan must be in place at all times.

(c) Written procedures must exist that:

1. Describe the procedure for correction of data entry errors. The system must include a mechanism to:

- a. Identify who corrected the data;
- b. Control access of who can correct data; and
- c. Monitor the number of changes for both reportable and non-reportable data.

NOTE: *If it is a reportable result, the results must be identified as "corrected."*

2. Describe methods for maintaining data integrity, including:
- a. An audit trail for changes in verified data;
 - b. Periodic checks on data integrity following both scheduled and unscheduled downtimes; and
 - c. The mechanism for reconstructing lost data.

3. Describe maintenance procedures for hardware and software. Maintenance must be regularly scheduled to have minimum impact on operations.

4. Define information security procedures developed by the laboratory staff with concurrence from the facility Information Security Officer (ISO). These procedures must detail who has access to:

- a. View data;
- b. Enter data;
- c. Edit data; and

d. Modify software. Only the national developers, through very stringent processes, can make modifications. Procedures must prohibit any local modifications to software.

NOTE: *If the procedure contains general statements by position, there must be a detailed listing with the names of individuals and their level of access.*

(d) Requests for official software modifications for blood bank software must be submitted on a change request form to VACO. **NOTE:** Local modifications are strictly prohibited.

(3) **Validation Testing.** Prior to the release of laboratory software, VBECS developers are required to subject the software to intensive testing and review as part of the development and verification process. A great deal of the functionality of software is affected by the operating system, interaction with other software packages in the same database, and files which accommodate local modification. This “verification” is not equivalent to “validation testing,” nor can it be substituted for mandatory “validation testing.” **NOTE:** *Additional details and a sample plan are included in the Blood Bank User Manual Appendix provided with the VA VBECS software.*

(a) In order to confirm that the computer software logic functions as desired using the local database, operating system, and hardware configuration, validation testing must be performed in accordance with the current requirements of the various accrediting and regulatory agencies. Computer systems used in blood establishments must be validated in accordance with current regulatory requirements and standards for equipment, such as the FDA (see 21 CFR Part 211 and 21 CFR Part 606), AABB standards, and CLIA (42 CFR Part 493).

1. A Validation Test Plan must exist which details the individual responsible for:

- a. Developing, executing, and reviewing results of test cases;
- b. Evaluating the validation process;
- c. Determining the acceptance criteria; and

d. Determining acceptability of testing.

2. The Validation Test Plan must address a variety of issues, including:

- a. The physical description of the computer hardware;
- b. The manufacturer and model;
- c. The number and location of terminals;
- d. The list of modems and authorized access to modems;
- e. The identity of any instrument interfaces;
- f. The internal interface (module to module) and external interfaces (peripheral, other application software, and network communications, etc.);
- g. The environmental conditions;
- h. The operating system and version;
- i. The application software and version;
- j. A listing of options and programs to which blood bank personnel have access;
- k. A summary of the implementation process, including action to be taken if deviations from expected performance occur; and
- l. The full variety of test cases. **NOTE:** *These test cases must ensure that all safety critical intended use functions have been included.*

3. The Validation Test Plan must define the acceptance criteria for the validation testing. Test plans must identify the input, the expected results, and an evaluation of the acceptability based upon a comparison of the actual results to the expected results. The criteria need to include:

- a. Definitions for successful completion of the test cases, as well as for when the user requirements will be met; and
- b. The process for evaluation of unaccepted occurrences to determine whether the occurrence is critical or non-critical.

(b) Validation testing must include testing of all control functions and routine operations under a variety of test conditions.

1. A control function is a system function that causes an activity to occur, or that influences the behavior of the user of the system. Control functions may exist even when competent human intervention occurs. Examples include functions in which

labels are created; records are created, modified, retrieved, deleted and/or archived; data is compared to a standard; or a warning message is generated.

2. For each control function, the spectrum of control must be indicated, i.e., process control or decision support.

a. Process control involves functions in which the system software actually makes a decision using available information and algorithms.

b. Decision support functions are those in which an individual bases a decision on information obtained from the system.

3. Routine operations are those used in the daily operations of the blood bank in that VA medical facility. **NOTE:** *Options, routines, or functions which are not utilized in that VA medical facility need not be tested.* These operations must include:

a. Data entry methods;

b. Information security procedures;

c. Program overrides;

d. Data storage; and

e. Retrieval and traceability of results.

4. A variety of test conditions must be addressed, including:

a. Normal data;

b. Exceptional data which provides an unusual twist for the program to force the program to react to data, or a situation that might be unexpected;

c. Boundary situations to force the evaluation of conditions that are of borderline validity;

d. Invalid data to force a program to prove that it can detect invalid input; and

e. Stress conditions, to determine whether the system has acceptable performance limits.

(c) Validation testing must be performed in an environment which must be a duplicate of the operating system file structure, programs, and site specific options, etc., of those found in production. Validation testing must be performed in a robust test account that is a fully patched mirror version of the production account.

(d) Validation testing must be performed in accordance with the specified time frames, as well as the requirements outlined by VA and various regulatory agencies:

1. Retrospective validation is required for current systems and/or software in operation before the FDA memorandum of September 1989. This validation testing must include the full scope of testing detailed in paragraph 14.g.(3)(b).

2. Prospective validation testing must be performed before software is put into use for daily operations. This testing must be completed before parallel manual systems are discontinued.

3. Prospective change control validation testing must be performed before revisions or modifications in software are in use for daily operations. This validation testing may encompass a more limited scope depending on the nature of the change and the interaction of the specific routine on other functions. Hazard analysis must be performed when changes occur, in order to determine the scope of validation. This analysis is done to identify the critical processes, operating, and performance parameters affected by the change and, hence, that require validation.

(e) Validation testing must be documented in a comprehensive manner.

1. Testing documentation must include observations from testing. This may be in the form of:

- a. Work sheets;
- b. Screen prints;
- c. Logging files;
- d. Printed reports;
- e. Written transcriptions;
- f. Data tapes; or
- g. Data disks.

2. Testing documentation must include proof of a review of the test cases, whether testing met the acceptance criteria or required any corrective action, the signature and date of approval by the Chief or Director of the blood bank section, and the implementation date.

(4) Tracking of Errors.

(a) A record or log must exist to detail unusual occurrences and errors ("bugs"). Documentation must include:

1. All safety critical anomalies (bugs) or anything observed in the documentation or operation of the computer or software that deviates from expectations based on performance, or reference documents;

2. Clinical significance of errors;
3. Corrective action taken to resolve the problem; and
4. Final resolution.

(b) Unusual occurrences and errors must be evaluated by the Laboratory Information Manager (LIM) or the VA medical facility IT Service to determine whether the problem is local or whether it involves the released version of the software.

1. All errors related to the released version of the software must be immediately reported to the VBECS software developers using the appropriate complaint handling system (e.g., Remedy).

2. Errors related to local database problems are to be resolved by the LIM, the VA medical facility IT Service, or the supporting Information Office (OI) staff.

(c) In the event that an error exists, or the software does not perform a necessary control function, immediate action must be taken to report the problem so that an appropriate work-around can be developed and implemented until the problem can be permanently resolved. This includes any error which allows the inappropriate release and distribution of unsuitable blood and blood components.

(5) Training of Personnel.

(a) All persons utilizing the computer must undergo appropriate training prior to performance of duties involving the VBECS, or comparable computer software.

(b) Ongoing assessment of personnel competency must include the use of the computer software.

(c) Prior to the implementation of software changes, all users of the blood bank software must be trained in the changes as part of the validation testing.

(6) Documentation.

(a) There must be a written record of unscheduled downtimes, including the reason for failure and any corrective action taken. **NOTE:** *This need not necessarily be maintained in the blood bank.*

(b) In accordance with the provisions of paragraphs 14.g.(3)(e) and 14.g.(4), there must be documentation of validation testing and of the errors which occur either during validation testing or after implementation.

(c) Documentation of training must be maintained.

15. SURGICAL PATHOLOGY, CYTOPATHOLOGY AND ELECTRON MICROSCOPY TESTING

a. Scope.

(1) **Anatomic Pathology.** The practice of anatomic pathology includes surgical pathology, cytopathology, immunohistochemistry, diagnostic EM, Mohs surgery, and autopsy pathology.

(a) Diagnostic services in anatomic pathology must provide timely, conveniently available, accurate and clinically useful, descriptive, evaluative and complete diagnoses for all anatomic specimens obtained in the VA medical facility and its outreach functions.

(b) Services must be provided to facilitate timely work-up and treatment of disease processes.

(c) Only qualified, licensed, and locally privileged pathologists certified by the American Board of Pathology in Anatomic Pathology can provide the written report for all surgical pathology, autopsy, diagnostic EM, non-GYN cytopathology and abnormal GYN cytopathology examinations. The Chief or Director, P&LMS must have a process to assess performance for all individuals performing anatomic pathology activities at VA.

(d) The following exceptions may be made when the individual is deemed competent by the local Chief or Director, P&LMS and the individual is privileged within the VA medical facility to provide the specific pathology report within their specialty.

1. Oral pathology reports may be reported through pathology by dentists board certified in Oral and Maxillofacial Pathology.

2. Mohs cases may be reported through pathology by physicians who are board certified by the American Board of Dermatology with board certification in dermatopathology or certified by the American Board of Dermatology and fellowship trained by American College of Mohs Surgery in Procedural Dermatology – Mohs.

3. Dermatopathology may be reported through pathology by physicians who are certified by the American Board of Dermatology/American Board of Pathology with fellowship and board certification in Dermatopathology.

4. Neuropathology reports may be reported through pathology by physicians who are board certified in neuropathology by the American Board of Pathology.

5. Hematopathology reports may be reported through pathology by physicians who are board certified in hematology by the American Board of Pathology.

6. A qualified, licensed, and locally privileged pathologist board certified in anatomic pathology by an equivalent accrediting organization approved by the VA P&LMS National Director may provide anatomic pathology reports.

(e) VACO arranges for programs for ongoing QM, and as appropriate, PT in surgical pathology and cytopathology in each VA medical facility that performs these services.

(2) **Surgical Pathology.** VA medical facilities must provide surgical pathology services (either on-site, through contract, or sharing agreement) on tissue specimens obtained from patients. Surgical pathology services must include frozen as well as routine sectioning, and special staining, including immunohistochemistry.

(a) **Review of Outside Pathological Material.** When patients are to receive treatment at a VA facility based on tissue samples obtained elsewhere (either at another VA facility or non-VA facility), VA pathologists at the facility where the patient will receive treatment must review and issue a report on the slides of all specimens obtained outside the local VA so that the diagnosis can be confirmed. Any treatment or procedure on the patient should not be performed until confirmation of the diagnosis has been obtained. The patient's clinical provider is responsible to request and obtain the outside tissue slides. It is not the local P&LMS responsibility to request the outside pathological material. The patient's clinical provider will follow local procedures to request "Release of Information" (i.e., the tissue slides) from the other VA or non-VA source of the patient's tissue slides. The outside tissue slides should be sent to the local P&LMS with a SF 515 completed by the patient's clinical physician for accessioning, examination, and reporting in as timely a manner as possible.

(b) All tissue, foreign bodies, and other specimens removed from patients are to be referred to the P&LMS for examination, unless specifically exempted by the clinical governing body of the facility.

1. The laboratory must have a policy that addresses a patient request that specimens be returned to them after a surgical procedures. Whenever possible the laboratory should make an effort to accommodate religious needs. The local policy should specifically address under what circumstances and what types and conditions specimens may be returned.

2. Diagnostic requirements must be met prior to the release of specimens.

3. The local policy must be reviewed by VA Regional Counsel prior to implementation.

(c) Each laboratory must establish and monitor the expected turnaround time for routine surgical pathology and non-GYN cytopathology reports. Turnaround time must be defined based on needs and requirements of the VA medical facility and in agreement with medical staff. The suggested benchmark for routine testing is 2 working days when testing is performed on-site.

(3) **Cytopathology.** Cytopathology services must be provided either on-site, through contract, or sharing agreement. If cytopathology services are provided, standard methods for processing all types of cytology specimens must be available.

(a) All cytology specimens obtained at VA medical facilities must be sent to P&LMS for evaluation and diagnosis.

(b) All screening of VA GYN cytopathology slides must physically be performed in the laboratory of the medical facility providing the review. The only exception is situations in which the laboratory does not have enough GYN cytopathology cases to hire a full-time cytotechnologist and the cytotechnologist is shared with another facility. In this case:

1. The cytotechnologist must be located at another VA and perform screening under an Intra-agency Agreement between the two VA laboratories; or

2. The cytotechnologist must be an employee of the pathology group providing cytology services for the VA. When the cytotechnologist is located at a contract site, the pathologist signing the case must be credentialed at both the VA and the contract site.

3. Both the sites where screening occurs and where cases are signed out must be accredited for GYN cytopathology.

4. The name and address of the lab where the slide is screened must also be included in the final report.

(c) No person who screens GYN cytopathology slides may screen more than 100 slides per 24-hour period. This count includes any screening they perform for other employers or at another facility. All persons in P&LMS who screen cytopathology slides must meet the qualifications in 42 CFR Part 493.

(d) All non-GYN and abnormal GYN cytopathology specimens must be evaluated and diagnosed by a qualified pathologist.

(e) Cytopathology reports of GYN specimens are to be completed within 14 working days.

(f) Negative GYN cytopathology specimens may be reported by cytotechnologists when:

1. The cytotechnologist meets the qualifications of 42 CFR 493.1483; and

2. The Chief or Director, P&LMS has certified the competency of the cytotechnologist to report negative GYN cytopathology specimens by written delegation; and

3. At least 10 percent of the cytotechnologist's gynecologic cases that have been interpreted as negative are routinely rescreened, and are diagnosed and documented as being negative by a qualified pathologist; and

4. The cases subjected for rescreening must include some cases from high-risk patients, as well as random negative cases, based upon criteria established by the Chief or Director, P&LMS.

(4) **Mohs Surgery.** **NOTE:** *Mohs surgery is named for Frederic E. Mohs who, as a medical student, developed this microscopically-controlled removal of skin tumor. All VA sites where Mohs surgery, microsurgery for cutaneous carcinomas involving frozen sections, or any surgical procedure in which frozen sections are used for the diagnosis or guiding treatment of patients, must be included as part of the main laboratory accrediting process or the site must maintain current accreditation by a VA designated, nationally-recognized, CMS “deemed” accrediting body.*

(a) Individuals performing the histopathology for Mohs surgery must meet the requirements in 42 CFR 493.1449.

(b) All diagnostic reviews of these frozen sections must be documented in the medical record.

(c) All residual specimens, including all slides, frozen section blocks, and any unsectioned tissue must be fixed and forwarded to pathology for retention.

(d) All Mohs cases must be accessioned and reported in pathology (VistA).

(e) Only physicians approved and deemed competent to read Mohs frozen sections by the local Chief or Director, P&LMS, privileged within the medical center to perform Mohs surgery or pathology, and with the following board certifications may provide Mohs pathology reports in VistA.

1. Board certified in anatomic pathology by American Board of Pathology; or
2. Certified by American Board of Dermatology with board certification in Dermatopathology; or

3. Certified by American Board of Dermatology and fellowship trained by American College of Mohs Surgery in Procedural Dermatology – Mohs Surgery.

(f) All Mohs surgeries that do not have a previous diagnosis documented in VistA by a pathologist board certified in Anatomic Pathology by the American Board of Pathology or a dermatopathologist certified by American Board of Dermatology with certification in Dermatopathology must undergo a second review by a pathologist.

(g) The Chief or Director, P&LMS, must ensure that a random retrospective second review for quality management is performed on 10 percent of all Mohs surgeries and for all individuals providing Mohs pathology reports.

(h) If a Mohs laboratory is not included as part of the main laboratory accrediting process, the Chief of Staff must ensure that a 10 percent random retrospective second review for quality management review is performed for all Mohs surgeries.

NOTE: *A peer review for quality management is protected under 38 U.S.C. 5705 and its implementing regulations.*

(i) The Chief or Director, P&LMS must ensure that all Mohs slides and tissue are retained accordance with all applicable accreditation standards and VHA standards as defined in the VHA P&LMS Retention Requirements document located on the P&LMS website at: http://vaww.lab.med.va.gov/References_Directives_and_Regulations.asp.

NOTE: *This is an internal VA Web site that is not available to the public.*

(j) VA facilities that obtain Mohs surgery services (contract or sharing) from a non-VA organization must ensure that the organization providing such services has a current, valid CLIA certificate and is appropriately accredited for specific frozen section services.

b. **Responsibilities of the Chief or Director, P&LMS.** The Chief or Director, P&LMS is responsible for:

(1) The ongoing professional and technical aspects of anatomic pathology;

(2) Ensuring that individual performance appraisals are performed for all staff performing anatomic pathology activities; and

(3) Actively participating in the appraisal process.

c. **Anatomic Pathology Program Requirements.** P&LMS must have an ongoing mechanism for monitoring and evaluating those aspects of care that are most important to the health and safety of the patient, including:

(1) The communication of surgical pathology and cytopathology diagnoses (including significant report modifications) to attending physicians and medical personnel authorized to receive or transmit diagnoses.

(2) Any potential and actual detrimental patient outcomes resulting from delays in surgical pathology or cytopathology diagnoses.

(3) Any potential and actual detrimental patient outcomes resulting from incorrect surgical pathology or cytopathology diagnoses.

d. **Evaluation of Anatomic Pathology Specimens.**

(1) At the time of evaluation of all anatomic pathology specimens, a complete summary of all previous specimens obtained from the patient at the local VA medical facility, and their diagnoses must be available to aid in interpretation of the current specimen. Relevant clinical history, and if possible, relevant anatomic pathology specimen preparations from other health care providers, must be obtained and reviewed prior to final evaluation. This includes documentation of consultations and a review of pertinent VA patient material previously obtained from other health care providers.

(2) If VA anatomic pathology specimens are not evaluated on-site, the laboratory where specimens are evaluated must be currently accredited by an appropriate, nationally-recognized CMS “deemed” accrediting body and have a Certificate of

Accreditation issued by Department of Health and Human Services (HHS) under the provisions of CLIA.

(a) Reports of such specimen evaluations must be transcribed onto SF 515, Tissue Examination, or the laboratory module of VistA and authenticated by the Chief or Director, P&LMS, or a VA staff pathologist.

(b) These reports must include the name and address of the facility where the evaluation was performed, as well as the name of the pathologist at that facility responsible for the evaluation.

(c) These reports must follow the standards for anatomic pathology reports generated at the VA medical facility, as well as all applicable federal requirements and standards.

(d) All contract pathologists must meet the same qualifications to sign out anatomic pathology specimens as a VA staff pathologist according to the requirements of this Handbook.

e. **QM, Quality Review, and PT Programs.**

(1) QM in anatomic pathology, including surgical pathology, cytopathology, diagnostic EM, and autopsy pathology, focuses on mechanisms to maintain and improve the quality of care for VA patients. Emphasis should be given to those factors shown to generate the greatest potential of risk to the patient and those most important to patient care. **NOTE:** *Quality management activities generate confidential documents that are protected as defined in 38 U.S.C. 5705 and its implementing regulations.*

(2) To be included in each local VA medical facility's Quality Management Program are mandatory external Quality Review Programs, and as appropriate, PT Programs in anatomic pathology. These programs are arranged and monitored by the National Director, P&LMS, and include, but are not limited to, the following:

(a) An external surgical pathology review program; and

(b) A non-GYN cytopathology program, as specified by the National Director, P&LMS (e.g., the American Society of Clinical Pathologists (ASCP) non-GYN assessment program); and

(c) A CMS-approved GYN cytopathology PT program; and

(d) Additional similar programs, which may be included at the discretion of each local Chief or Director, P&LMS.

f. **Functions of Anatomic Pathology External Quality Review and PT Programs.**

(1) Quality Review and PT programs are intended to identify laboratories and individuals who are unable to reliably distinguish clinically important findings and report

them in a conventional manner to communicate the important finding(s) to the patient's provider.

(2) Quality Review and PT programs must include all the diagnostic activities of anatomic pathology services provided at each VA medical facility and by each individual responsible for reporting anatomic pathology material at that medical facility.

(a) These programs must:

1. Be designed to identify deficiencies resulting from inadequate experience, education, or training.

a. After identification of deficiencies, lead to focused reviews and additional education and training as required to remedy the deficiency.

b. Continually improve the anatomic pathology services provided.

c. Proficiency will not be a static yardstick, but must reflect the local, current, and changing conditions of diagnostic standards.

d. These programs are not to be used to evaluate degrees of expertise.

2. Adhere to principles established by recognized authorities on the inherent limitations of the administrative process.

3. Be an element to determine competency of the specific activities performed at a VA medical facility and by an individual. If the activity is diagnostic, testing should identify the inability to recognize and distinguish clinically important diagnostic categories or abnormalities.

4. The test materials must be evaluated in the routine manner for patient specimens from that VA medical facility.

(b) Testing material must:

1. Reflect the case mix, patient demographics, and disease profiles of patients in the VA health care system; and

2. Be reviewed by a panel of pathologists or come from sources with recognized expertise with the specific specimens.

(c) P&LMS in VACO is responsible for:

1. Arranging for an approved Quality Review and PT program for assessment in surgical pathology and cytopathology.

2. Providing proficiency review of the Diagnostic EM Programs in P&LMS, when indicated.

3. Administering the Quality Review and PT programs. Reports of medical facility and individual performance must be submitted annually to the Chief or Director, P&LMS, at each VA medical facility providing anatomic pathology service.

4. Overseeing the activities of each VA medical facility's anatomic pathology service. **NOTE:** *If indicated, performance reviews are to be conducted and corrective action implemented to ensure that each P&LMS continues to provide high standards of service and patient care. Since peer reviews for quality management are protected under 38 U.S.C. 5705 and performance reviews are not protected, when transitioning from a peer review for quality management to a performance review process, only the initial summary of the occurrence can be communicated in order to ensure there is a distinct separation of the protected and non-protected processes.*

(3) The Chief or Director, P&LMS is responsible for recognizing the need for additional education or training, based on the reports of performance and the results of the Quality Review program.

g. Accession and Examination of Specimens.

(1) All specimens removed during surgical procedures must be sent to P&LMS for evaluation by a qualified pathologist unless specifically exempted by the governing body of the facility.

(a) Cytology specimens obtained at the VA medical facility (both outpatient and inpatient) must be sent to P&LMS for accessioning.

(b) Processing and evaluation of specimens must be directed by a qualified pathologist.

(c) All tissue and cytology specimens sent to P&LMS must be accompanied by an appropriately completed SF 515 or authorized equivalent.

(2) If any anatomic pathology material is sent to another facility for medical-legal examination, full identification is required and the chain of custody must be preserved.

(3) Any exception to the policy of sending all specimens removed during a surgical procedure to P&LMS for examination by a pathologist must be with the written approval of the VA medical facility's Clinical Executive Committee or equivalent, and the laboratory performing the examination must meet the accreditation standards of The Joint Commission and CAP.

(4) If the evaluation of any anatomic pathology specimen concludes that there is malignancy and that there has been no prior definitive diagnosis of that malignancy (excluding skin squamous and basal cell carcinomas), the patient's provider or surrogate practitioner must be personally notified by verbal communication as soon as possible (ideally, within 1 working day of the time that diagnosis was made).

(a) These communications must be documented in the specimen report by the pathologist who notifies the patient's provider.

(b) Electronic communication (e.g., view alerts, local VistA, Email, etc.) may be utilized, but only in addition to the required verbal communication.

(c) A “new diagnosis of malignancy pathology progress note” in the electronic medical record, i.e., Computerized Patient Record System (CPRS), may also be used. Designating the patient’s provider as an “additional signer” to the “new diagnosis of malignancy pathology progress note” in CPRS affords a mechanism to validate that the message has been received and read by the patient’s provider.

(5) All frozen section diagnoses that do not agree with the diagnosis on the permanent section must be reviewed and documented in the patient report.

(6) All cases with unexpected diagnoses of clinical significance, and diagnoses of malignancy not previously established (excluding skin squamous and basal cell carcinomas), must be reviewed by a second pathologist prior to issuance of the final report and concurrence by the second pathologist must be documented on the final report.

(a) Preliminary reports may be issued while the review by a second pathologist is being obtained.

(b) In cases where there is only a single pathologist on site, the second review should be performed within 48 to 72 hours.

(c) In cases where there is only a single pathologist on site and where long distances between medical facilities, inclement weather, or logistical problems preclude review within 48 to 72 hours, the second review must be performed as soon as possible, preferably no more than 7 to 10 days from the first diagnosis.

h. **Recovery and Disposition of Implantable Medical Devices.** Implantable medical devices removed from inside the body of a patient should be submitted to the P&LMS for accessioning and examination. Pacemakers, implantable defibrillators, or other prosthetic devices may be submitted to P&LMS either as a surgical specimen or as an autopsy specimen. In either event, the following procedure should be followed:

(1) Appropriately accession the device as either a surgical or autopsy specimen, and prepare a concise gross description of the device including:

- (a) Manufacturer;
- (b) Model number;
- (c) Serial number; and
- (d) Other relevant description.

(2) Report the gross description in the tissue examination report or autopsy report as appropriate.

(3) Secure the device in a biohazard bag.

(4) Follow the local policy for the notification of the local designated service responsible for tracking implantable devices (Sterile Processing Services (SPS) and/or prosthetic service). After the completion of the tissue exam, deliver the device with a copy of the SF 515 to the designated service as directed locally for disposition.

i. **Internal Quality Review - Mandated Second Peer Review of Cases for Quality Management.** The Chief or Director, P&LMS must ensure that a random retrospective quality management peer review of surgical, fine needle aspirates, Mohs surgery and cytopathology cases is performed by a second pathologist on at least a quarterly basis for a minimum of 10 percent of all surgical pathology cases, fine needle aspirates, and cytopathology cases diagnosed in that medical facility.

(1) In VA medical facilities with two or more pathologists, second reviews should be arranged within the staff. In cases where there is disagreement, a third opinion must be obtained expeditiously, either from local consultants, such as pathologists at an affiliated medical school or from Joint Pathology Center (JPC), with a request for consultation. If there is a significant change in diagnosis that affects the patient's treatment, the Chief or Director, P&LMS advises the Chief of Staff or Director of Clinical Services and the patient's physician or an appropriate clinical staff provider who must take action to contact the patient and revise or amend the treatment.

(2) In VA medical facilities with only one pathologist, a documented, signed second review must be obtained on at least 10 percent of all surgical, fine needle aspirations, and cytopathology cases. The second opinion must be obtained through one or a combination of the following:

(a) Local consultants, or

(b) Another VA medical facility with a pathologist on its staff, or

(c) The JPC through the VA-JPC Memorandum of Agreement; see section 23a.

(3) In VA medical facilities with no permanent pathologist, the Chief of Staff ensures that the second review of all surgical pathology and cytopathology diagnoses is provided by a qualified pathologist (board certified, licensed, and experienced in anatomic pathology). The 10 percent review system is also mandated for contract or sharing agreement pathologists who provide surgical pathology, or cytopathology diagnostic services for VA medical facilities.

NOTE: *Electronic or paper dated log books and documentation of second reviews are to be maintained in the VA medical facility's P&LMS in accordance with the requirements of VHA Records Control Schedule 10-1, Section VIII- Laboratory Service (113). The records must contain or document provider specific information.*

(4) Only qualified individuals credentialed and privileged to perform and provide anatomic pathology reports within their specialty as outlined in paragraph 15.a.(1)(c) and (d) of this Handbook may perform a second review within that specialty.

(a) Individuals performing a second review in GYN cytology must have achieved a current successful GYN cytology competency assessment.

(b) In no case will a resident physician act as a second reviewer for a staff pathologist. Similarly, a review of a resident physician's diagnosis by a staff pathologist does not constitute a second review in this context.

NOTE: *Peer review processes for quality management are protected under 38 U.S.C. 5705 and its implementing regulations. A quality management review may be used to prompt a performance review. Since peer reviews for quality management are protected under 38 U.S.C. 5705 and performance reviews are not protected, when transitioning from a peer review for quality management to a performance review process, only the initial report or summary of the occurrence can be communicated in order to ensure there is a distinct separation of the protected and non-protected processes.*

j. **Anatomic Pathology Reporting and Specimen Slide Storage.**

(1) **Reports.** Authenticated and dated reports of examination of all anatomic pathology specimens submitted to P&LMS become part of the patient's record. Diagnostic reports must be issued expeditiously to the patient's record for review by the provider who submitted the specimen. **NOTE:** *Duplicate copies of all reports are to be kept by P&LMS in a readily retrievable manner. As electronic distribution and storage systems are implemented, these systems may be used in lieu of copy storage as long as all the information on the report is captured in the electronic storage system, and all accreditation standards are met.*

(2) **Examination Reports.** The report for all surgical pathology and cytopathology specimen examinations must be on a SF 515, or in VistA; it must be legible and it must include:

- (a) Full patient identification;
- (b) Identity of the patient's provider;
- (c) Identity of the submitting provider;
- (d) Date and nature of the procedure used to obtain the specimen;
- (e) Type and location (organ) of the specimen;
- (f) Pertinent clinical information and other information contained on the requisition;
- (g) Identity (name and address) of the VA medical facility where the specimen was processed;

(h) Unique accession number of the specimen;

(i) Date and text of the pathological evaluation;

(j) Name and authentication of the responsible pathologist. **NOTE:** *Authentication constitutes a wet signature in the case of paper reports or electronic signature for digital reports;*

(k) All special procedures performed and consultations obtained; and

(l) The names of all pathologists who reviewed, or contributed to, the evaluation of the specimen. **NOTE:** *In retrospective peer reviews, the name of the reviewing pathologist does not have to be added to the report unless the review necessitates a change to the released report.*

(3) **Cytopathology Report.** If cytology slides are screened by someone other than the responsible pathologist, the final cytopathology report must include the name of that person.

(4) **Copies.** Only authenticated copies of diagnostic anatomic pathology reports with the patient's name, unique identifier, name and address of the VA medical facility, and the name of the staff pathologist can be produced and circulated outside of P&LMS. Whether P&LMS or the medical records department of the medical center releases copies of reports is determined by local policy.

(5) **Terminology.** All diagnoses must be descriptive, and are intended to communicate clinically relevant information using standard terminology and nomenclature.

(6) **Additions to Report.** Grading and specific information, when clinically important to aid in staging, are to be included in the report. **NOTE:** *For cancer cases, the CAP "cancer protocols" provide examples of the pertinent information to be included in the report.*

(7) **Coding.** All diagnoses must be coded using Systematized Nomenclature of Medicine (SNOMED) to facilitate data retrieval; however, these codes are not to be used as a substitute for the descriptive diagnoses. **NOTE:** *Nondescript letter or numeric codes are not to be used for cytopathology diagnoses in reports.*

(8) **Surgical Pathology Report.** The final surgical pathology report must, in addition to the items in paragraph 15.j.(2), include:

(a) A description of the specimen received;

(b) The written text of any verbal reports of consultations and frozen section examination; and

(c) The date of verbal notification of a diagnosis of malignancy and the name of the provider or responsible person contacted.

(9) Modification and Supplemental Additions to Released Reports.

(a) Once released to the medical record, any modification or supplemental addition to the final anatomic pathology report must be clearly indicated, as well as the person responsible for the modification, and the date of the modification. The original information must also be retrievable.

(b) If the modification, or supplemental addition, is clinically significant, the patient's health care provider and the submitting physician must be immediately notified of the modification and the issuance of a new report. If the change in diagnosis affects the patient's treatment, the Chief or Director, P&LMS must also advise the Chief of Staff or Director of Clinical Services.

(10) Retention and Disposal. Retention and disposal of P&LMS copies of anatomic pathology reports are to be in accordance with all applicable Federal standards (e.g., the VA Record Control System (RCS 10-1) and accreditation requirements). The retention and disposal of slides, specimens and/or tissue are to be in accordance with accreditation requirements and VHA P&LMS retention requirements (located on the P&LMS website at: [http://vawww.lab.med.va.gov/References Directives and Regulations.asp](http://vawww.lab.med.va.gov/References_Directives_and_Regulations.asp)). The RCS 10-1 is the definitive guide for retention of reports, but the accreditation standards, as well as the following guidelines generally apply.

(a) Authenticated electronic reports or a copy of the authenticated reports must be retained for a minimum of 25 years.

(b) Wet stock of surgical specimens, and submitted cytology material must be retained for at least 2 weeks after the date of the final report. When they no longer serve a useful purpose, wet stock of surgical specimens, and submitted cytology material must be disposed of under the responsibility of the Chief or Director, P&LMS.

(c) Representative glass slides and electron microscopic materials must be retained for a minimum of 25 years, with the exception that negative or unsatisfactory GYN cytopathology slides may be retained for a minimum of 5 years.

(d) Representative paraffin and plastic blocks must be retained for a minimum of 10 years. It is recommended that paraffin blocks from suspicious or positive cases be retained longer when space permits.

k. **Data Processing for Anatomic Pathology.** VistA is the computer system for anatomic pathology; it must conform to the requirements of CAP, The Joint Commission, and VA policy.

l. Immunohistochemistry.

(1) In some laboratories, immunohistochemistry functions are an important adjunct to the conventional techniques used in anatomic pathology. While immunohistochemical procedures are more complex and difficult to perform properly

than many "special stains," immunohistochemical results must, like other histochemical procedures, be interpreted in the context of all of the available information (e.g., clinical history, gross findings, light microscopy, EM, etc.), and do not stand alone.

(2) Accordingly, the policies and procedures outlined in the Quality Management Program also apply to immunohistochemical procedures.

(a) Test methodologies must be validated

(b) Immunohistochemical stains must be incorporated into PT programs as appropriate for the types of cases under review.

(c) As positive and negative control sections are routinely prepared with each immunohistochemistry run, these may need to be included in order to interpret the PT slide correctly. **NOTE:** *PT, which includes immunohistochemistry should not be done in laboratories that do not use immunohistochemistry.*

m. **Discontinuation or Merger of Anatomic Pathology Services.** When anatomical pathology services at a VA facility are discontinued or merged with another VA facility, all documentation and specimens which are required to be maintained must be transferred to the VA facility where the scope of services for the patients of that facility has been transferred.

n. **Diagnostic EM in Laboratory Services.** Electron Microscopy Diagnostic EM services must be provided regionally at VA facilities.

(1) EM, an important element in diagnostic pathology, must be provided for renal pathology and when needed for difficult diagnostic cases. EM services can be provided in the following ways:

(a) Establishment of a diagnostic EM Program in selected VA medical facilities;

(b) Shared use of EM resources acquired primarily for research or education purposes;

(c) Referral of material for ultrastructural study to another VA medical facility with EM resources in the geographic area; and

(d) Referral of material to or use of EM resources in an affiliated medical facility or community hospital after establishment of a formal agreement for those services.

(2) Functions of a diagnostic EM Program in the P&LMS include:

(a) Enhancement of morphologic diagnosis;

(b) Provision of diagnostic EM services at the parent hospital and to other VA facilities in the geographic area;

(c) Provision of training in EM for professional and technical personnel;

(d) Inclusion, where appropriate, of the EM findings in facility teaching and conferences; and

(e) Development, where indicated, of sharing agreements to provide EM services for non-VA medical institutions.

(3) The following steps must be followed to apply for an EM Program:

(a) VA medical facilities wishing to establish a diagnostic EM Program in P&LMS must prepare an application in accordance with the current requirements (which may be obtained from the National EM Program Coordinator (113), VA medical facility, Durham, NC 27705).

(b) The application must be transmitted through the VISN Director's Office with a statement from the VA medical facility Director expressing approval and certification that the proposed EM resource will not create a redundancy.

(c) There must be a preliminary review of the application for completeness by the National EM Program Coordinator.

(d) The application must be reviewed by the Ad Hoc EM Review Group on the merit of the proposal, and a recommendation made to the National Director, P&LMS. **NOTE:** *A site visit may be included in the analysis of the proposal by members of the review group.*

(e) If an application proposes joint usage for research or educational purposes, the National Coordinator must refer the application to the appropriate departments in VACO for review and comment.

(4) Basic and recurring support of a diagnostic EM Program must be provided by the VISN. This includes, but is not limited to:

(a) Basic funding for a diagnostic EM resource with initial and recurring components. Initially, funds must be planned for acquisition of equipment and, if required, support for necessary construction must be planned before the application is submitted.

(b) Recurring support requires funds for personnel, supplies, and a service contract. The cost of the service contract is normally prorated among users other than P&LMS, for example, as Research and Development working with Education Service through a Structured Joint Utilization Agreement.

1. A full program requires a full-time pathologist and 2.0 FTE technical staff.
2. Programs approved at half-level require a 0.5 FTE pathologist and 1.0 FTE technical staff.
3. Cost of supplies for a half-level program is usually 50 percent of the regular level.

(c) Support for EM programs, including replacement of equipment, must be funded by the VA medical facility or that facility's VISN resource or funding distribution process.

(5) Each EM unit must have a qualified pathologist as a Program Chief or Director who is expected to devote sufficient time and effort each week to diagnostic EM to ensure an effective program.

1. The Program Director should be an academician with excellent skills and training in anatomic pathology and documented interest in research and teaching.

2. Board certification in anatomic pathology is required. At least 1 year of experience in EM, preferably diagnostic EM is strongly suggested.

3. Board certification in clinical pathology is not required, but is desirable, since EM laboratories need to serve the entire laboratory in applications, for example, in hematology and microbiology.

4. Additional subspecialty board certification in relevant areas, such as cytopathology, neuropathology, microbiology, hematology, etc., is not required, but is useful.

(6) A VA medical facility must meet the following criteria in order to be considered for national, regional, or VISN status as a diagnostic EM Program:

(a) A demonstrated interest and expertise of the physician-pathologist staff in EM and detailed specific documented plans for use of the resources in diagnostic pathology.

(b) Sufficient volume and variety of patient-related material to support a diagnostic EM program.

(c) An active pathology residency training program and supportive medical school affiliation in pathology.

(d) Active pathologist participation in facility teaching conferences and plans for presentation of relevant EM findings at conferences.

(e) Plans for shared use of the diagnostic EM resources for research and educational purposes.

(f) Documentation that EM needs cannot be met through existing VA resources, the affiliated medical facility, or the community.

o. **Operations of a Diagnostic EM Unit.** An approved operational EM Unit is considered a permanent addition to the VA medical facility's P&LMS provided the utilization or productivity and quality of EM services remain satisfactory, as judged by the VA National EM Coordinator.

(1) Records and Reports.

(a) Specimens transmitted for EM study are accessioned and documented appropriately.

1. A written or electronic report must be issued promptly on each patient specimen using VistA and the CPRS, or if electronic entry is not available, on the SF 515, and placed in the patient's record within 10 working days after study is requested for cases where ultra-structural findings are of clinical significance. Ideally, a verbal report of the clinically pertinent EM findings should be provided to the patient's health care provider within 3 working days after the EM study is requested. The date and content of this verbal report must be noted in the written report.

2. The report must include:

a. Dates of accession and diagnosis;

b. A description of the light and electron microscopic findings;

c. A specific diagnosis; and

d. Where appropriate, the pertinent literature reference.

3. The report must be signed by the pathologist making the diagnosis. **NOTE:** *Electron micrograph prints or digital images need not be distributed or included routinely with the reports. Selected digital images of excellent quality and key diagnostic value may be uploaded through VistA Imaging and attached to the patient electronic health record via CPRS.*

(b) Files maintained in the EM Unit must include:

1. A chronologically numbered accession record giving the date each specimen is accessioned. **NOTE:** *All specimens, patient referral, research, and teaching, must be logged in using the appropriate available options on the VistA system.*

2. The date of diagnosis and the anatomic source of each specimen.

3. An indexed file of diagnostic reports correlated with electron micrographs or digital images.

(c) Records Retention. Specimens, slides, and records must be retained in accordance with the requirements of VHA Records Control Schedule 10-1, Section VIII-Laboratory Service (113), CLIA, AABB, CAP, and TJC or other deemed status accrediting organization, whichever is the most stringent. **NOTE:** *Electronic distribution and storage may be used in lieu of hard copy storage as long as all the information on the hard copies is captured in the electronic storage system, and all accreditation standards are met.* For EM materials, these guidelines are specified in Table 1:

TABLE 1. RETENTION OF EM SPECIMENS AND RECORDS

ITEM	FORMAT	RETENTION
<u>1.</u> Wet tissue		Must be retained 2 weeks after final report
<u>2.</u> Plastic Blocks		Must be retained 25 years from date of exam
<u>3.</u> Semi-thin section (glass slides)		Must be retained 25 years from date of exam
<u>4.</u> EM Grids		Must be retained 1 year from date of exam
<u>5.</u> Reports	Written only (no electronic version)	Must be retained 25 years after final report
	Electronic (VistA, CPRS)	Retained within patient electronic record 75 years after last episode of care ^(a)
<u>6.</u> Accession Record	Written only (no electronic version)	Must be retained 5 years after specimen receipt
	Electronic (VistA)	Must be retained 25 years after specimen receipt
<u>7.</u> Maintenance records		Must be retained 2 calendar years
<u>8.</u> a. Negatives		Must be retained 25 years after final report
b. Digital Images	Electronic (selected images uploaded to VistA Imaging, CPRS)	Retained within patient electronic record 75 years after last episode of care. Electronic Final Version of Health Record, Destroy/Delete 75 years after the last episode of patient care. Final, consolidated, electronic version of a Patient Medical Record. Includes information migrated from interim electronic information systems, electronic medical equipment, or information entered directly into the patient medical record information system. May be stored on optical disks or other magnetic media.
	Electronic (all images, local	Must be retained 25 years

ITEM	FORMAT	RETENTION
	EM Unit archive with optical or other media back-ups)	after final report
<u>9.</u> Prints from negatives included with report	Written (only) report or electronic report	Must be retained 10 years along with the report
<u>10.</u> Remaining prints from negatives	Written (only) report or electronic report	Must be retained 1 year after final report

(d) Numerical (productivity) data from the EM program are reported monthly in LMIP by using the VistA workload reporting module for P&LMS.

(e) Annual reports are required from each EM Unit in P&LMS.

1. The reports are be prepared by the program Chief or Director, EM Unit, and transmitted through the Chief or Director, P&LMS and the medical facility director, to the National EM Program Coordinator.

2. The reports must be prepared in accordance with the prescribed format furnished by the National EM Program Coordinator.

3. The reports must be completed and dispatched by the 20th working day of October each year.

(2) **Monitoring.**

(a) Appropriate safety monitoring procedures for emission of radiation from each electron microscope must be established in keeping with the existing VHA safety policy (see VHA Handbook 7701.01, Occupational Safety and Health (OSH) Program Procedures).

(b) Quality monitoring will utilize the following procedures:

1. Analysis of the numerical data in the workload section of the VistA Laboratory Module;

2. Analysis of the annual report; and

3. Assessments by the Ad Hoc EM Review Group, annually and on an as needed basis.

(3) **Sharing Resources.** The shared utilization of EM resources for diagnostic, research, and education purposes is encouraged to promote maximum effective capacity.

(a) Such arrangements, buying, selling, or exchanged use, which include appropriate pro-rating of recurring costs, may be developed locally, pursuant to 38

U.S.C. 8153, VA Directive 1663, Health Care Resources Contracting-Buying, and VHA Handbook 1660.01, Health Care Resources Sharing Authority- Selling. To the extent that VA resources are furnished to non-VA parties, first priority shall be given to critical diagnostic needs of VA patients.

(b) EM reports on patient specimens received from non-VA medical facilities through sharing agreements, and on which a diagnosis is rendered and a report issued, constitute patient services and are to be billed accordingly.

1. This policy applies even though the specimens may also be used for teaching and research.

2. The charges for the services provided must be established so that the VA medical facility is able to recover its costs.

(c) The contents of the agreements must be concurred upon, by the:

1. Chief or Director, P&LMS;

2. The individual responsible for research and development at the facility;

3. The individual responsible for education at the facility; and

4. Chief of Staff, Director of Clinical Services, or Director of Medical Staff.

(d) Completed agreements must be forwarded to the medical center Director for review and approval and executed in accordance with policies established in VHA Handbooks and Directives; see paragraph (3)(a) above.

(4) **Quality Management.**

(a) As Diagnostic EM usually functions as an adjunct to conventional anatomic pathology techniques, the policies and procedures for continuing quality assessment and improvement outlined also apply to diagnostic EM. Certain aspects of the EM Program are unique. Quality assessment is achieved through a national peer review process, in addition to local reviews. The data from these indicators are evaluated to identify opportunities for improvement.

(b) The primary peer review quality management review requires that annually each EM Program submit five review cases, which meet the following criteria:

1. They are clinically justified EM cases which state why the case was processed for EM examination and what the ultra-structural exam was expected to resolve beyond what was accessible in prior pathology reports or diagnoses using light microscopy, immunochemistry, or other techniques. **NOTE:** *Cases where the use of EM was primarily for confirmation of previous diagnostic findings are not to be included in the five annual review cases.*

2. Specifically state what the ultra-structural findings of clinical significance were.

(c) Assessment of the quality of EM examinations must be the principal monitoring tool for the evaluation of diagnostic and technical proficiency of the EM Program. Though a certain number of EM cases should be processed and reported in order to maintain diagnostic and technical proficiency, no specific minimum number is required. However, numerical productivity and cost efficiency can be monitored using the LMIP statistical tools available to staff at the local facility level and using the national LMIP workload data accumulated at the Corporate Data Center Operations (CDCO) Austin, TX. A peer group, the Ad Hoc EM Review Group, is responsible for assessing the quality of cases from each diagnostic EM Program through annual review. Attention is given to:

1. The quality of the electron micrographs;
2. The description of the findings in the report;
3. The accuracy of the diagnosis and the clinical significance of the ultrastructural findings; and
4. The citation of literature references, when appropriate.

(d) Determination of satisfactory performance depends upon satisfying the peer group in regard to quality.

NOTE: *The peer quality management review processes are protected under 38 U.S.C. 5705 and its implementing regulations. A quality management review may be used to prompt a performance review. However, since a peer review for quality management is protected, it cannot be substituted for a performance review.*

(e) These resources may be supplemented as indicated by requests for additional information and occasionally by site visits.

1. Annually, the National Director, P&LMS, prepares letters containing an evaluation of each diagnostic EM Program and concluding with the assigned rating. These letters are sent to the VISN Director.

2. When a program is rated as unsatisfactory, a probationary status is assigned.

a. The probationary status usually prevails for 1 year to allow time for correction of the deficiencies.

b. Failure to correct the deficiencies within the 1-year grace period may result in orderly closure of the diagnostic EM Program. In some instances where the productivity or utilization criteria are not met, although the quality is satisfactory, a decision may be reached during, or at the conclusion of the probationary period to reduce the program from full to half level.

NOTE: *The VISN or medical facility Director, during the grace period, may decide after consultation with the medical staff Director, the Chief or Director, P&LMS, and the program Chief or Director of the EM Units, that patient care needs could be met as well*

by closing the EM Unit and obtaining the services from another VA or non-VA facility. In such instances, the medical facility Director must discuss the local decision with the National Director, P&LMS, before any final action for closure is taken.

(5) VACO EM Program Responsibilities.

(a) P&LMS, VACO, has the responsibility for fulfilling the following functions:

1. Collection and analysis of utilization data from all electron microscopes assigned to P&LMS;
2. Promotion of maximal joint utilization of electron microscopes for diagnostic purposes, and advice on structured joint utilization agreements;
3. Recommendations on relocation of under-utilized electron microscopes;
4. Recommendations to VISNs on the need for additional, or replacement, electron microscopes; and
5. Maintenance of a current inventory of all electron microscopes assigned to P&LMS.

(b) The Under Secretary for Health approved the establishment of an EM Ad Hoc Review Group with membership composed of VA and non-VA pathologists having expertise in the specialty of EM.

1. The group is chaired by VA's EM Coordinator and serves in an expert advisory capacity to the National Director, P&LMS.
2. The group's primary functions are to:
 - a. Assess the quality of diagnostic EM;
 - b. Review applications for new diagnostic EM Units and make recommendations to the National Director, P&LMS; and
 - c. In special situations, review selected annual reports and participate in site visits to EM Units.

(c) If EM laboratories offer special expertise, equipment, or procedures to other VA medical facilities and their sharing agreement partners, the National Director, P&LMS, may designate particular diagnostic EM programs as benchmark Centers of Excellence.

1. The primary goal of a Center of Excellence is to serve as a benchmark for other EM facilities and to facilitate the sharing of the capabilities available in these special laboratories with other VA medical facilities.
2. The National EM Coordinator acts as the principal expert in determining which centers are chosen.

16. POST-MORTEM EXAMINATION

a. **Scope.** All VA medical facilities must provide post-mortem examination services (either on-site, through contract, or sharing agreement). If these services are not available at a particular VA medical facility, arrangements must be made for autopsies to be performed at another VA or other non-VA facility. The availability of these services must be made known to the family of each decedent. The medical staff is required to request authorization for post-mortem examination in all deaths, consistent with the requirements of 38 CFR 17.170 and VHA Handbook 1601B.04.

(1) The Director of Clinical Services or Chief of Staff of the medical facility is responsible to the medical center Director for overall management of post-mortem examination services. The management responsibilities include:

(a) Arrangements for securing post-mortem examination authorizations consistent with 38 CFR 17.170. **NOTE:** *It is VHA policy that permission to perform a post mortem examination must be requested in every instance when a patient dies while an inpatient at a VA facility or under the immediate care of a VA facility;*

(b) Ensures restricted autopsy examinations (those limited to a specific area, i.e., brain and spinal cord, chest cavity, or abdominal cavity) meet the requirements for autopsy.

(c) Provision of sufficient competent staff for the examinations and for timely completion of post-mortem examination reports;

(d) Maintenance of suitable facilities and appropriate coordination with funeral directors and local authorities; and

(e) Ensures autopsies of cases of infection with high risk pathogens are performed using appropriate personal protective equipment, environmental controls, and proper decontamination procedures commensurate with the biosafety precautions indicated for the known or suspected pathogen. If the Chief or Director, P&LMS cannot ensure or comply with appropriate biosafety precautions, there must be a local policy, approved by the medical staff, to guide if and how autopsies on cases of infection with high risk pathogens are conducted. This local policy must comply with all of the biosafety precautions indicated for the known or suspected pathogen, as well as with all of the other requirements of this Handbook.

(f) Ensuring that post-mortem examination findings become a continuing component of the VA medical facility's internal monitoring of medical practice.

(g) Ensuring an alternative to performing autopsies at the medical facility is provided. This service may be contracted to another VA or accredited non-VA facility. **NOTE:** *Establishment of Regional Autopsy Centers at VISN or multi-VISN level may provide access to a quality and cost-effective alternative.*

(2) Findings from all post-mortem examinations must be presented to the medical staff on a regular basis, as expeditiously as possible. Such reviews must occur with the frequency appropriate to the level of activity in the medical center, but at least once each quarter. The reviews could take the form of a traditional conference or reports to an appropriate medical staff committee (e.g., quality of care committee).

(3) The Chief or Director, P&LMS, is responsible for the direction of professional aspects of post-mortem examination, including:

- (a) The custody of bodies co-signed to the post-mortem examination suite;
- (b) Performance of the post-mortem examination and the diagnoses;
- (c) Preparation of protocols and reports (provisional and final);
- (d) Retention and disposition of post-mortem examination tissue (blocks, microscopic slides); and
- (e) Professional support of clinical and administrative activities related to the post-mortem examination.

(4) In all instances legal consent must be obtained prior to conducting a post-mortem examination and in a manner consistent with the terms of 38 CFR 17.170 and VHA Handbook 1601B.04, Decedent Affairs.

(a) The original copy of the authorization, SF 523, Authorization for Autopsy, or transcript of recorded telephone conversation, must be included in the deceased's medical record. For iMed SF 523s supportive documents may be entered in the form of a linked progress note.

(b) Under certain circumstances, detailed in 38 CFR 17.170 (a) (2) (ii-iv), the Director of that VA facility may cause an autopsy to be performed based on implied consent of the decedent's surviving spouse or next of kin.

b. **Autopsy of Veterans Who Die Outside of a VA Facility.** The Director of a VA facility may order an autopsy on a Veteran who was under VA treatment or care authorized under the VA Non-VA Medical Care Program and who dies outside of a VA facility if the Director obtains consent pursuant to 38 CFR 17.170 (d) and determines that such autopsy is reasonably required for VA purposes for the completion of official records or the advancement of medical knowledge. Such authority also includes transporting the body at VA's expense to the facility where the autopsy will be performed, and the return of the body. If all of these conditions can be met, the local P&LMS will perform the post-mortem examination following routine procedures.

c. **Post-Mortem Examination Rates as a Percentage of Hospital Deaths.** VA policy for post-mortem examination rates encourages the maximum number of post-mortem examinations within a wide range of clinical categories, rather than to seek an arbitrary fixed post-mortem examination rate as a percentage of all hospital deaths. Particular emphasis should be exerted to obtain permission for the autopsy of

unexpected deaths and deaths proximate to interventional procedures (refer to current VHA policy).

d. **Deaths with Medical-Legal Significance.** Deaths suspected of resulting from crime that occur in a VA medical facility are of potential medical-legal significance. These deaths may be called “medical examiner” or “coroner's cases” (“ME/C cases”). These cases must be reported to the appropriate official(s) and autopsies pursued only, in accordance with requirements of 38 CFR Sections 17.170 (b), (c), (d) and consistent with the terms of 38 U.S.C. Sections 5701(f) (2) and 7332, and the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule.

(1) In cases where the United States does not have exclusive jurisdiction over the area where the body was found, the medical examiner or coroner is to be informed. If the medical examiner or coroner assumes jurisdiction, that official is responsible for the performance of the autopsy. In all instances in which VA intends to transfer patient information to the coroner or medical examiner, VHA must request Regional Counsel review to ensure that authority exists in all applicable statutes, per above, before releasing the information.

(2) In cases where the United States has jurisdiction over the area where the body is found, the Director of the VA facility must inform the Office of Inspector General (OIG) of the known facts concerning the death. The OIG will transmit all such information to the United States Attorney for such action as may be deemed appropriate and will inquire whether the United States Attorney objects to an autopsy which otherwise would be appropriate. If the United States Attorney has no objection, the autopsy may be performed as if the death had not been reported, that is, pursuant to the terms of section 17.170 (a) and (b).

(3) VA Regional Counsel must be consulted if there is any question whether a death should or should not be reported to the local coroner or medical examiner.

(4) If the coroner determines that the death is of natural circumstances and releases the decedent's remains, an autopsy may be done at the VA facility pursuant to the terms of section 17.170(a) and (b) governing non-ME/C cases. ***NOTE: There is no requirement for preservation of “chain of custody” in non-coroner and coroner refused autopsies.***

e. **Deaths for which the JPC has established Special Registries.**

(1) Certain groups of Veterans may yield valuable findings at post-mortem examination. These groups include the following Veterans:

- (a) Former Prisoners of War (POW);
- (b) Agent Orange/Vietnam Service (AGO);
- (c) Kuwait/Persian Gulf War Service 1990-1991 (KUW);
- (d) Operation Iraqi Freedom/Iraq Service 2003-2011 (IRQ); or

(e) Operation Enduring Freedom/Afghanistan Service 2001-Present (AFG).

(2) Guidelines for performing post-mortem examinations on Veterans belonging to these groups are available in Appendix B. See also paragraph 16.j below for information on additional consent requirements related to use of autopsy specimens for diagnosis, scientific, or therapeutic purposes.

(3) A duplicate set of slides, blocks and representative wet tissue must be forwarded to the JPC for each of the above listed groups of Veterans, in addition to the customary local examination and reporting of pathologic material.

(4) All cases submitted to the JPC Registries must be submitted on the JPC Registry Submission, Acknowledgment and Receipt Form, JPC Form 543. The form can be located on the JPC website at: <http://www.jpc.capmed.mil/>. If consultation is requested from the JPC, including neuropathological examination, a JPC consultation form must accompany the material on which consultation is requested.

(5) All material shipped to JPC must be packed according to applicable regulations and instructions as outlined in the JPC Manual located on the JPC Web site at: <http://www.jpc.capmed.mil/>.

f. **Performance of the Post-Mortem Examination.**

(1) A complete clinical record and a listing of clinical questions or concerns related to possible post-mortem examination findings must be furnished to the pathologist by the clinical attending physician prior to beginning the post-mortem examination.

(2) The gross post-mortem examination must be performed under the supervision of a qualified, licensed, credentialed physician, usually a pathologist qualified in anatomic pathology.

(a) Some of the activities may be delegated to suitably trained allied health personnel; however, only under the direct, personal supervision of a qualified pathologist.

(b) Members of the house staff who perform post-mortem examination must be under the supervision of a pathologist.

(3) There must be a positive identification of the deceased by the pathologist who checks the name and other identifying data attached to the deceased, and compare these with information recorded on SF 523.

(4) There will be strict adherence to the family's wishes as recorded on the SF 523.

(5) Care must be exercised that there is no undue delay in performing the post-mortem examination which would inconvenience the family of the decedent.

(6) As soon as possible, the pathologist is to notify the attending physician of the time of post-mortem examination and arrange for a demonstration of the gross findings.

(7) The post-mortem examination should be conducted prior to embalming. Embalming prior to post-mortem examination, whether by arterial injection or by intracavitary trocar injection, is not to be done because of the risk of these procedures causing anatomic alterations, making it impossible to determine if these changes preceded embalming.

(8) Universal precautions must be exercised at all times.

(9) Post-mortem examination (normally encompassing both gross and microscopic studies) must be conducted in a professional manner. The objective of these examinations is the full exposition of the patient's disease processes, the limits thereof, and the patient's response to therapy.

(a) The body will be left in the best possible condition.

(b) Special examinations, when specifically authorized, must be coordinated with appropriate funeral directors and VA authorities, as indicated.

(c) Authorization for removal of organ or tissue for donation is accomplished by completion of SF 523B, Authorization for Tissue Donation and proceeding according to local medical center policies.

(10) Photographic documentation, an essential component of the post-mortem examination, must be readily available.

g. Post-Mortem Examination Reports.

(1) Within 2 working days, provisional anatomic diagnoses must be entered into VistA for hospital personnel to view, with an alert or a copy forwarded to the Chief or Director of the appropriate clinical service, and the patient's provider.

(2) The Chief or Director, P&LMS, is responsible for establishing and maintaining a system for coding diagnoses, thereby enabling retrieval and compilation of cases in VistA. Final post-mortem examination diagnoses must be coded using SNOMED.

(3) The completed post-mortem examination, with final copy of succeeding pages, must be made a part of the patient's medical record within 30 working days, unless exceptions for special studies are established by the medical staff.

(4) The format and extent of the gross and microscopic descriptions depends upon local practices, but sufficient information must be included to support the diagnoses rendered.

(5) The following form of the post-mortem examination protocol is suggested as likely to correspond to clinical interest:

(a) Clinical diagnoses;

(b) Final anatomic diagnoses, including neuropathologic findings;

- (c) Gross and microscopic findings, including clinical summary;
- (d) Discussion to correlate clinical and post-mortem information; and
- (e) Draft of lay letter to next-of-kin, if requested.

(6) Only a qualified licensed pathologist, board certified in anatomic pathology, can provide a final written diagnosis for gross and microscopic post-mortem examination findings.

(7) The original SF 503 or equivalent must be included in the patient's medical record, and a copy of the post-mortem report (paper or electronic) must be retained by the P&LMS.

(8) The Chief or Director, P&LMS, must provide the Chief of Staff or Director of Clinical Services for the medical facility with a copy of the post-mortem examination report in any case in which the post-mortem examination findings raise the possibility of a claim against VA.

- (9) A post mortem quality assurance survey must be completed.

NOTE: *The post-mortem quality assurance survey is an "autopsy review" which is a quality management activity that has been designated as protected by 38 U.S.C. 5705 and cannot be part of the medical record. Therefore, post-mortem examination findings covered as a quality management activity must be disclosed only in accordance with the disclosure provisions of 38 U.S.C. Section 5705. The post-mortem examination report (SF503) clinical findings is a part of the medical record and is not 38 U.S.C. 5705-protected. The release is governed by the laws and regulations that apply to medical records. The VHA Privacy Officer and/or Freedom of Information Act (FOIA) Officer is to be consulted whenever there is a request for any of these documents.*

h. **Recovery and Disposition of Implantable Medical Devices.** Pacemakers, implantable defibrillators, and other prosthetic devices recovered in post-mortem procedures should be handled in the same manner as outlined for surgical pathology in paragraph 15.h.

i. **Quality Management in the Post-Mortem Examination Service.**

(1) Performance standards must be established by the Chief or Director, P&LMS, at each medical facility to ensure the:

- (a) Pathologists' skills are sufficient;
- (b) Post-mortem examination is performed accurately; and
- (c) Post-mortem examination report addresses the questions of clinical concern to the patient's health care provider.

(2) The post-mortem examination can be used as an outcome measure to assess clinical diagnostic accuracy (see Appendix A).

NOTE: *The Post-Mortem Quality Assurance Survey (Appendix A) is a protected quality management activity and, when warranted, may be used to prompt a performance review. However, since the quality management is protected, it cannot be substituted for a performance review.*

j. **Use of Post-Mortem Examination Tissues for Diagnostic, Scientific, or Therapeutic Purposes.** The SF 523 makes provision for the removal and retention of tissues for diagnostic, scientific or therapeutic purposes.

(1) If the autopsy procedure is to include the removal of tissues not covered by permits in the VA medical facility, a SF 523B must be executed by the person authorized to grant permission for autopsy.

(2) Special permission must be obtained for removal of organs and tissues for transplantation.

(3) Research using tissues or organs removed at autopsy must be in conformity with a written protocol approved by the local Research and Development Committee and by its Subcommittee on Human Studies before the research begins.

k. **Confidential Treatment of Post-Mortem Examination Records**

(1) If tissues or records are to be sent from VA for examination in non-VA laboratories or by investigators, such persons can be given access to such items only within the restrictions imposed by laws governing the disclosure of information, e.g., the Privacy Act of 1974, 38 U.S.C. Sections 5701, and 7332.

(2) Some of the preceding statutes address the disclosure of information about patients in an individual identifiable format. If the examiner requires that the slides and records contain the Veteran's name or other confidential information, there must be a prior written agreement that:

(a) The recipient of the slides and records will not disclose any information in an identifiable form without prior specific VA authorization;

(b) Information will be safeguarded from disclosure; and

(c) The slides and records will be returned to VA when there is no longer a need for the recipient to retain them in order to accomplish the purpose for which they were originally supplied.

(3) Specimens may be retained after completion of the post-mortem examination and presented at conferences. Cases with unusual findings may be sent to the JPC as a consultation case. JPC will provide organ-specific consultation on autopsy material. The JPC will not provide consultation on entire autopsies and will not perform autopsies.

Autopsy materials must be sent to the JPC according to the standard procedures outlined in the JPC Manual at <http://www.jpc.capmed.mil/>.

(4) Use of photographs to record gross and microscopic features is encouraged. Files of photographs are to be retained as long as they are considered to be useful.

(5) Museum specimens, post-mortem materials retained for authorized research projects, and organized teaching collections may be exempted from the retention provisions.

I. **Monthly Autopsy Report.** Each VA inpatient facility laboratory (acute and long-term care) must complete the VA form 10-0424, Monthly Autopsy Report and submit it to the National Director of P&LMS in VACO, no later than 30 days after the end of each month being reported. **NOTE:** *VA Form 10-0424, Monthly Autopsy Report form can be found on the VA Forms Web site at: <http://vawww.va.gov/vaforms>. This is an internal VA Web site that is not available to the public.*

17. JOINT PATHOLOGY CENTER (JPC) REFERENCE LABORATORY SERVICES

a. **Scope.** VA P&LMS Program established a Memorandum of Agreement (MOA) pursuant to the VA-DoD Health Care Resources Sharing Authorities, 38 U.S.C. 8111 and 10 U.S.C. 1104, with JPC for anatomic pathology secondary consultation services. The MOA between JPC and VHA specifies that consultation services and ancillary testing will be the financial responsibility of the submitting VA medical facility. This paragraph provides direction and guidance to VA medical facilities regarding the use of JPC reference laboratories.

b. **Joint Pathology Consulting Services.** As established by the MOA, VA laboratories may submit anatomic pathology cases to the JPC for second opinion consultation. The JPC does not provide primary human pathology services (with the exception of nerve, muscle, renal biopsies, and electron microscopic evaluation of cilia motility disorders). Cases submitted for consultation must be submitted according to the standard procedures outlined in the JPC Manual (located on the JPC Web site at <http://www.jpc.capmed.mil/> under the consultation tab) and this Handbook.

(1) **Surgical Pathology Submissions.** The materials for surgical pathology consultation must be submitted according the instructions outlined in the JPC Contributor's Manual located in the JPC Web site at <http://www.jpc.capmed.mil/> under the consultation tab. A completed JPC Contributor's Consultation Request Form must accompany each submission.

(2) **Telepathology.** Limited telepathology secondary consultation is available, under prior arrangement, to a limited number of facilities. All telepathology services will be provided as secondary consultation. The JPC will not provide primary pathology services or frozen section 'second reads' by telepathology.

(3) **JPC General Surgical Pathology Consultation Policies.**

(a) JPC personnel are prohibited from rendering an opinion, written or verbal, on any non-accessioned case. All cases for which an opinion is being sought must be submitted for accessioning to the JPC.

(b) All pathology consultation records maintained by the JPC are protected by the Privacy Act and by the regulations implementing the HIPAA. A copy of the JPC Privacy Act Systems Notice for our pathology consultation case files is available upon request or from the Defense Privacy Office. The JPC falls under the DoD Notice of Privacy Practices. This notice can be found on the JPC web site at www.jpc.capmed.mil.

(c) The JPC does not accept non-federal civilian consultation cases on human tissue.

(d) The JPC does not accept Human cases involving Cytology, Perinatal, Neonatal, and Placental Pathology.

(e) The JPC does not have a Chemical Pathology Service and is unable to offer consultation on calculi of any kind.

(f) Accessioned cases and associated materials are, in the absence of clear information to the contrary, will be considered to have been transferred irrevocably to the JPC by gift or other conveyance from an individual or entity with the authority to make such a transfer, and become the property of the JPC when the case is accessioned. Generally, cases will not be accepted if the contributor requests return of all pathologic materials.

(4) Consultation Questions or Comments.

(a) Inquiries concerning the status of a case recently submitted to the JPC should be directed to Customer Service at 1-855-393-3904. The JPC office will be able to provide the following information about a case if it has already been accessioned:

1. The date the case was accessioned;
2. The JPC accession number assigned;
3. Materials received; and
4. Whether or not the case has been completed.

(b) Requests concerning inactive cases and material should be directed to Customer Service at 1-855-393-3904.

(c) Inquiries may also be submitted via the JPC website, www.jpc.capmed.mil to jpchelp@amedd.army.mil. All inquiries containing patient information must be encrypted. The JPC is unable to respond to unencrypted messages containing patient information.

(5) **Reporting of Cases Sent to JPC.** The Chief or Director, P&LMS, must ensure that the number of surgical pathology and consultation cases sent to the JPC are recorded appropriately in the workload recording module of the facility's VistA.

c. **Special Death Registries.** The JPC has established Special Death Registries for POW, AGO, KUW, IRQ, and AFG. Instructions for submission to these registries are in found in the Post-Mortem Examination, paragraph 16.c. (2).

d. **Packaging of Biologic Materials.** All diagnostic or clinical specimens shipped to JPC must be packed according to applicable regulations and instructions as outlined in The JPC Manual located on the JPC Web site at: <http://www.jpc.capmed.mil/>.

18. INFECTIOUS DISEASES, INFECTION CONTROL, AND EPIDEMIOLOGY

a. **Scope.**

(1) This paragraph provides direction and guidance to VA medical facilities regarding infectious diseases, infection control, and epidemiology testing. **NOTE:** *Non-laboratory personnel often perform this testing.*

(2) All VA laboratories and ancillary testing sites are required to:

(a) Comply with current VA Directives and other applicable standards related to infection control.

(b) Facilitate infection control activities and investigations.

(c) Ensure that cost-effective culturing is implemented throughout the facility.

(d) Maintain the proper engineering controls, work practices, and the use of biological safety cabinets and personal protective equipment, where appropriate, in order to reduce the potential for aerosol spread of infectious microorganisms to patients, visitors, and VA employees.

(e) Investigate food-borne illnesses.

b. **Facility Infection Control Activities.** Infection prevention and control activities may be conducted by a functional group or an Infection Prevention and Control Committee. This group provides oversight for the review of culture results, develops tolerance limits and intervention strategies, and develops corollary investigations when intervention is unsuccessful.

(1) **Representation.** Each main clinical laboratory must have a permanent representative on the facility Infection Control Committee. It is recommended that the Chief or Director, P&LMS, the supervisor of the microbiology section (or other laboratory personnel knowledgeable about environmental cultures, pseudoepidemics, and other microbiological phenomena) serve on the Infection Control Committee.

(2) **Reports.** Each laboratory must work with the Infection Control Committee or the facility Infection Control Officer to determine the infection control reports to be generated periodically to support the needs of the organization and to define the required frequency of the reports. These reports must include:

(a) Numbers and identification of microorganisms found in cultures with results of cumulative antibiotic susceptibility. **NOTE:** *An assessment of antibiotic resistance trends must be included. Minimum frequency: yearly*

(b) Microorganisms that must be reported to local or state boards of health. *Minimum frequency: monthly or as required according to local and federal requirements.*

(c) Organisms that necessitate special isolation procedures (e.g., multiple antibiotic resistant organisms). *Minimum frequency: should be determined in consultation with the Multi-drug resistant organism (MDRO) Prevention Coordinator and the Infectious Disease, Infection Prevention, and Control Staff, and current VA guidelines.*

(d) Monitors for skin contaminants in blood cultures. *Minimum frequency: quarterly.*

(e) Biological indicator (spore test) results on autoclaves throughout the facility.

(f) Results of infection control cultures, particularly *Legionella* as it is now an organizational Management of the Laboratory Environment standard for The Joint Commission. *Minimum frequency: according to VA and accreditation guidelines.*

(g) Other quality management reports, as appropriate.

NOTE: *The above quality management reports are confidential documents that are protected as defined in 38 U.S.C. 5705 and its implementing regulations.*

c. **Food-Borne Illnesses.** If food-borne illness is suspected among VA employees or patients, the laboratory should consult the appropriate local, state, or Federal public health service laboratory for epidemiological and laboratory assistance.

19. BIOSECURITY AND BIOSAFETY PROCEDURES

a. **Scope.**

(1) All laboratories within VA that test patients for the diagnosis, treatment, and prevention of disease must meet the applicable clinical laboratory requirements for handling select agents defined in 42 CFR Part 73. The clinical laboratory requirements and exemptions are generally defined under 42 CFR 73.5 and 42 CFR 73.6.

(2) Where applicable, the laboratories must also meet any requirements for handling select agents, any security measures, hazardous materials and waste management measures, and emergency management procedures as defined by the following organizations: The Joint Commission, CAP, AABB, Center for Disease Control (CDC),

FDA, OSHA, Department of Transportation (DOT), Department of Health and Human Services (HHS), and the NRC.

(3) In accordance with guidance previously described in paragraph 4, all clinical laboratory testing sites, regardless of location, must undergo an on-site inspection by a CMS and VA-approved accrediting agency.

(4) All applicable clinical laboratory requirements of 42 CFR Part 73 and appropriate accreditation standards must be met for any laboratory services offered within a VA medical facility and outreach clinics, regardless of the physical relationship to the main P&LMS, or the administrative service assigned to direct the personnel, research, or technical aspects of the test site.

b. **Clinical Laboratory Standards.**

(1) **Laboratory Biosafety Level (BSL).** The CDC defines a biohazard as: "An agent of biological origin that has the capacity to produce deleterious effects on humans, i.e., microorganisms, toxins, and allergens derived from those organisms; and allergens and toxins derived from higher plants and animals." The following four basic classifications for these biohazards are defined as:

(a) BSL-1, i.e., agents not known to cause disease.

(b) BSL-2, i.e., agents associated with human disease.

(c) BSL-3, i.e., indigenous or exotic agents associated with human disease and with potential for aerosol transmission.

(d) BSL-4, i.e., dangerous or exotic agents of a life threatening nature.

(2) **Biological Safety Cabinets.** Biological safety cabinets are categorized as three basic types: Class I; Class II; and Class III. These cabinets are designed to protect laboratory personnel from aerosols created in handling and manipulating biological agents. The cabinets afford increasing protection as the class of the cabinet increases and the required class of the cabinet is selected based upon the hazard of the agent, the need for protection of personnel, and the extent to which aerosols may be produced. For most microbiological organisms encountered in clinical laboratories, generally a Class I or Class II cabinet is more than adequate.

(a) Since control of any aerosols produced depends upon proper biological safety cabinet performance, certification is necessary:

1. At initial installation and annually;

2. After moving a cabinet; and

3. After replacing a high efficiency particulate air (HEPA) filter.

(b) The certification procedure must include:

1. A leak test to ensure the air flow plenums are gas tight;
2. Measuring the air inflow velocity;
3. Measuring the airflow within the cabinet (uniform and unidirectional); and
4. A leak test of the HEPA filter to ensure that it is properly installed and leak-free.

NOTE: *Under no circumstances should a biological safety cabinet ever be moved or the filter changed before the cabinet and ductwork are properly decontaminated. The cabinet is never to be placed back into service, until it has been properly certified.*

(3) Requirements and Personnel Standards. The laboratory requirements and personnel standards are defined for each of the 4 basic classifications and increasingly stringent for the laboratories from BSL-1 through BSL-4. A combination of administrative controls, engineering controls, and personal protective equipment may be used to minimize employee exposure to bio-hazardous materials in the laboratory setting. An applicable reference that defines the specific laboratory requirements for each BSL is the fifth edition of the CDC and National Institutes of Health (NIH) Biosafety in Microbiological and Biomedical Laboratories (the CDC-NIH Manual).

(4) BSL-3 Practices.

(a) All existing VA laboratories performing diagnostic procedures involving the propagation of an agent that calls for BSL-3 practices for identification, typing, and susceptibility must be fully BSL-3 compliant or must cease such operations.

(b) All new laboratory sites implementing identification and testing procedures that require BSL-3 practices must not implement such procedures until the facility meets the full BSL-3 requirements.

(5) General Laboratory Procedures for Culturing Patient Specimens. Any clinical laboratory routinely culturing patient specimens for microbiological organisms must meet as a minimum, the BSL-2 facility and personnel training requirements defined in the CDC-NIH Manual.

(6) Laboratory Procedures for Performing Acid Fast Stains. As only BSL-2 practices and procedures are required for non-aerosol-producing manipulations of clinical specimens, such as preparation of acid-fast bacilli (AFB) smears for *Mycobacterium tuberculosis* (MTB), it is acceptable to carry out direct AFB smear staining procedures in a BSL-2 laboratory. Due to the risk of aerosols, any AFB smears prepared in a BSL-2 laboratory must, however, be limited to direct AFB smears only. Concentrated AFB smears are only to be prepared in a properly certified BSL-3 laboratory.

(7) Laboratory Procedures Associated With Aerosol Transmission. BSL-3 organisms as defined by the CDC, such as *Histoplasma*, *Coccidioides*, *Blastomyces*, and *Mycobacterium tuberculosis*, are potentially infectious to laboratory workers and staff, visitors, and patients of the medical facility by virtue of aerosol dissemination.

Employee screening, engineering controls, and personal protective equipment, as described in the following, can minimize the dangers.

(a) At low-exposure facilities (one that isolates and identifies cultures of any BSL-3 organisms from six or fewer patients per year), laboratory employees who are potentially exposed to *Mycobacterium tuberculosis* must be tested for exposure to this organism every year.

(b) At high-exposure facilities (one that isolates and identifies cultures of any BSL-3 organisms from more than six patients per year), laboratory employees who are potentially exposed to *Mycobacterium tuberculosis* must be tested for exposure to this organism every 6 months.

(c) In laboratories that routinely work with bacterial agents such as *Mycobacterium tuberculosis* in culture or with cultures that yield *Histoplasma capsulatum*, *Coccidioides immitis*, *Blastomyces dermatitidis*, or other BSL-3 agents, both the design and operation of the facility must adhere to the full BSL-3 facility requirements detailed in the CDC-NIH Manual.

c. **Site Requirements for Handling Select Agents.**

(1) **Select Agents Potentially Encountered in Clinical Laboratories.** In 42 CFR Part 73, a number of select agents and toxins are identified. However, the majority of these agents and toxins are not routinely encountered in most clinical laboratories. The agents of most relevance to clinical laboratories are the six pathogens that have been designated by the CDC as “Category A” diseases or agents and designated by HHS as Tier 1 agents. These are the organisms or toxins that are believed to pose the most risk to national security, as they may be easily cultured or acquired, present the greatest risk of deliberate misuse, and could result in high mortality rates or cause public panic. These Category A agents include *Bacillus anthracis*, *Clostridium botulinum* toxin, *Yersinia pestis*, smallpox (variola major), *Francisella tularensis*, and the agents causing viral hemorrhagic fevers (i.e., Ebola and Marburg viruses).

(2) **Select Agent Handling Requirements.** Special procedures are detailed in 42 CFR Part 73 and by CDC for culturing and handling these select agents. Those procedures applicable for clinical laboratories are summarized as follows: **NOTE:** Current additional information can also be found on the CDC Select Agent Program Web site at: <http://www.cdc.gov/od/sap/>.

(a) The clinical laboratory must immediately report to CDC any select agent or toxin identified as a result of diagnosis or verification.

1. The identification of any of the following HHS select agents or toxins must be immediately reported by telephone, facsimile, or e-mail: *Botulinum* neurotoxins, *Botulinum* neurotoxin-producing species of *Clostridium*, Ebola viruses, *Francisella tularensis*, Marburg virus, Variola major virus (Smallpox virus), Variola minor (*Alastrim*), or *Yersinia pestis*. This report must be followed by submission of the CDC Reporting The Identification Of A Select Agent or Toxin From s Clinical/Diagnostic Specimen Form

(APHIS/CDC Form 4A), within 7 calendar days after identification. The form and guidance for completing the form may be found at:

<http://www.selectagents.gov/CDForm.html>.

2. For all other HHS select agents or toxins, an APHIS/CDC Form 4A must be submitted within 7 calendar days after identification.

(b) Clinical laboratories must report to the CDC any select agent identified in a specimen presented for proficiency testing on the CDC/APHIS Proficiency Testing Identification Form, (APHIS/CDC Form 4B) within 90 calendar days of receipt of the select agent. The form and guidance for completing the form may be located at:

<http://www.selectagents.gov/CDForm.html>.

(c) Any reports required under applicable Federal, state, or local laws must also be immediately initiated.

(d) Upon completion of applicable patient testing or PT or transfer of the select agent to a facility eligible to receive them, the laboratory must appropriately destroy the culture or toxin and document the steps taken in this process.

1. The clinical laboratory is required to safely transfer or destroy the select agent or toxins used for diagnosis or testing within 7 days after identification unless directed otherwise by federal or other law enforcement officials. Any stock culture maintained during work-up for isolates referred to an outside laboratory for identification and that has been positively identified as a select agent, must be destroyed within 7 days of notification of these findings.

2. Select agents or toxins used for PT must be transferred or destroyed within 90 days after receipt.

(e) Copies of the completed APHIS/CDC Forms must be maintained by the laboratory for 3 years.

(3) **Security Requirements.** By design, clinical laboratories are open and accessible to clinicians and other members of the medical staff. Providers often come into the laboratory to review slides, other clinical materials, or to consult with the laboratory staff. While it is important to maintain an appropriate level of access, certain changes must be made in order to ensure that access to select agents is appropriately restricted.

(a) Department physical security requirements are codified in VA Directive 0730 and VA Handbook 0730, 0730/1 and 0730/2. Specific requirements are found in Handbook 0730/2, Appendix B. Areas where biohazardous materials, as defined by the CDC, are stored are found under the standards K, L, and M of the VA Handbook 0730/2, Appendix B matrix. The facility director, responsible for general facility security, must ensure that applicable facility modifications and other security measures defined in VA Directive 0730 and VA Handbooks 0730, 0730/1 and 0730/2 have been implemented.

(b) Any of the select agent organisms that are not absolutely required for patient care, PT, or educational purposes must be destroyed and the destruction documented. Once cultures of the listed organisms are identified, a clear audit trail must be maintained.

(c) When patient specimens and cultures are determined to contain any select agent organisms, they must be secured under lock and key anytime they are not being actively worked up.

(d) Access to the incubation, refrigeration, freezer, or other storage and work up areas for these select agents must only be accessible to authorized personnel.

(e) Clearly it would be prudent to restrict access to certain other high-risk areas of the laboratory that contain radioactive, toxic, or infectious materials. While many laboratories are already doing this, it also seems reasonable to conduct regular reviews and to revise laboratory specific security plans in conjunction with the facility's overall plan. Each Chief or Director, P&LMS must ensure that a laboratory risk assessment is conducted, a security plan is developed consistent with the requirements detailed in 42 CFR Part 73, and that local laboratory policies governing personnel and security procedures are well documented.

(f) Procedures for defining an approval process and updated lists for access to specific rooms or areas, procedures for security during "low-staffing" periods, notification procedures, etc., must be addressed.

(g) Added video surveillance may be applicable and may be of value for some clinical laboratories.

(h) Added security personnel may be required, particularly at some of the larger sites, to monitor and register personnel entering and leaving the laboratory. **NOTE:** *If added security measures are required (and due to the already constrained laboratory personnel resources) these general duties could be carried out, in most instances, by security guards.*

d. **Shipping Biological and Infectious Substances.**

(1) **Regulatory Requirements.** The regulations governing the packaging and shipment of biological, infectious, and hazardous substances are primarily found in the Federal Hazardous Materials Regulations, 49 CFR Parts 100-185 and the Transportation of Hazardous Materials; Driving And Parking Rules, 49 CFR Part 397. The parts of 49 CFR specifically dealing with biological and infectious specimens are 107, 171, 172, and 173. While the majority of shipments packaged and processed by the clinical laboratories are classified as diagnostic specimens, all specimens, as well as any select agents and toxins that are identified, must be packed and shipped in accordance with applicable guidance provided in 49 CFR.

(2) **Hazardous Materials and Security Training.** Personnel shipping hazardous materials (hazmat) must be aware of the potential use of hazmat for acts of terrorism

and are required to have documented transportation security awareness training. As many biological specimens are now classified as hazmat, it is important for all laboratory personnel involved in the packing and shipping of laboratory specimens to have hazmat training. While a number of commercial training programs are available to satisfy this requirement, a free training program is available from the DOT web site at http://hazmat.dot.gov/hmt_security.htm. It is the responsibility of each Chief or Director, P&LMS to ensure that all personnel who deal with specimen transportation and shipment receive this training.

20. ENVIRONMENTAL AND SAFETY ISSUES IN THE LABORATORY

a. Scope.

(1) This paragraph provides laboratory safety information to assist laboratories in designing complete safety programs in accordance with the requirements of VA and other Federal agencies.

(2) VA Directive 7700, Occupational Safety and Health, outlines VA policy for occupational safety and health. The laboratory safety program must be in full compliance with the requirements of the Occupational Safety and Health Act of 1970 (29 CFR Part 1910), Executive Order (EO) 11807, and guidelines issued by the Secretary of Labor under Section 3 of this Order. Further, each laboratory must have a designated Safety Officer.

b. Laboratory Safety Program.

(1) The Chief or Director, P&LMS, must ensure that a written safety program is developed and implemented which is in compliance with the requirements of VA policies, 29 CFR Part 1910, OSHA; 21 CFR Part 801, FDA; 49 CFR Part 172, DOT; 42 CFR Part 493, CMS; NRC; International Air Transport Association (IATA); The Joint Commission; CAP; AABB, or other applicable regulations or accreditation guidelines.

(2) The safety program includes: a safety manual; a Chemical Hygiene Plan (CHP) written in accordance with OSHA regulations (29 CFR 1910.1450, Appendix A); bloodborne pathogen and tuberculosis exposure control plans; a latex safety program; training in shipping and handling of hazardous goods, including certification of personnel who ship infectious substances; and any other safety requirements identified by regulation or accreditation standards.

(a) The CHP mandated for every laboratory that uses hazardous chemicals must include:

1. All operations that involve hazardous chemicals;
2. Criteria for use of personnel protective equipment;
3. Criteria for exposure monitoring;
4. Provisions for training employees in the CHP elements; and.

5. Access to Safety Data sheets (SDS) for all hazardous materials. **NOTE:** *Under the Globally Harmonized System of Classification and Labeling of Chemicals (GHS), the SDS has replaced the Material Safety Data Sheet (MSDS).*

(b) The safety manual must include, at a minimum, the following procedures:

1. Reporting accidents, injuries, and illnesses;
2. Fire prevention and control;
3. Electrical safety;
4. Chemical hazards;
5. Radiation hazards;
6. Microbiologic hazards (including infection control policies); and
7. Hazardous waste disposal.

(c) The exposure control plan must be developed in accordance with 29 CFR 1910.1030.

(3) A laboratory safety committee or the laboratory Safety Officer must:

(a) Ensure periodic inspection of the workplace and prompt elimination of unsafe conditions and actions;

(b) Review accident records;

(c) Ensure compliance with the safety program; and

(d) Report activities according to established facility protocols.

c. **Training.**

(1) All employees working within P&LMS must receive laboratory safety training in accordance with the VA Occupational Safety and Health (OSH) Program, the Laboratory Safety Program, and applicable OSHA requirements.

(2) Immuno-compromised employees or pregnant employees working in pathology and clinical laboratory settings should be evaluated for increased risk related to occupational exposures to infectious agents, medications, or chemicals. Individuals with unique health concerns should receive individualized counseling from their personal healthcare provider and their employer about the potential risks that may be associated with working in the clinical laboratory. Additional guidance may be found in the CDC Guidelines for Safe Work Practices in Human and Animal Diagnostic Laboratories; <http://www.cdc.gov/mmwr/preview/mmwrhtml/su6101a1.htm>

REQUIREMENT GUIDELINES FOR A POST-MORTEM QUALITY ASSURANCE SURVEY (AUTOPSY REVIEW)

The following is a list the information that should be included in a post-mortem quality assurance survey. This activity should be performed jointly by the pathologist and the clinician.

Patient's Name

Service

Social Security Number

Date

Department of Veterans Affairs (VA) Medical Center

Clinician

Pathologist

Autopsy Number

I. Clinical Pre-Mortem Diagnoses.

II. Post-Mortem Pathologic Diagnoses.

III. Findings Clinical Significance of Post-Mortem Appropriate Category.

- a. Major disagreement in diagnosis.
- b. Major unsuspected or additional diagnosis.
- c. Significant clarification of differential diagnosis, but no major disagreement.
 - (1) Diagnosis suspected, but not confirmed.
 - (2) Diagnosis among two or more equally considered.
- d. Confirmation or verification of major diagnosis.
- e. Autopsy indeterminate; does not clarify or resolve major issue.

IV. Clinical Factors Related to or Contributing to Cause of Death Appropriate Category.

- a. Unremitting course of disease.
- b. Error in judgment or treatment plan.

- c. Result of complication or therapeutic procedure.
- d. Unrecognized diagnosis with pre-mortem evidence, which existed by:
 - (1) Physical exam.
 - (2) Patient complaint or symptom.
 - (3) Clinical course.
 - (4) Inattention to or misinterpretation of diagnostic tests.
- e. Other.

V. Summary Comment.

Post-Mortem **Quality Assurance** Documentation is deemed **CONFIDENTIAL AND PRIVILEGED** under provisions of title 38 United States Code (U.S.C.) 5705, which provide for fines up to \$20,000 for unauthorized disclosures thereof, and the implementing regulations. Post-Mortem Survey documentation must not be transmitted to anyone without proper consent or other authorization as provided by law or regulation in title 38 Code of Federal Regulations (CFR) 17.500 through 17.511.

NOTE: *The above comment should be included on all pages the Autopsy Review Report.*

GUIDELINES FOR PERFORMING POST-MORTEM EXAMINATIONS ON FORMER PRISONERS OF WAR (POWs), AGENT ORANGE/VIETNAM SERVICE VETERANS, KUWAIT/PERSIAN GULF WAR VETERANS, OPERATION IRAQI FREEDOM/IRAQ SERVICE VETERANS, AND OPERATION ENDURING FREEDOM/AFGHANISTAN VETERANS.

1. Background.

a. A Special Registry was established in 1980 at the Armed Forces Institute of Pathology (AFIP) for pathological material from former Prisoners of War (POW) of World II, the Korean Conflict, and Vietnam Era. Four additional war-related registries have been added since then for Agent Orange/Vietnam service (AGO), Kuwait/Persian Gulf War service (KUW), Operation Iraqi Freedom/Iraq service (IRQ), and Operation Enduring Freedom/Afghanistan service (AFG). In 2011, the Joint Pathology Center (JPC) assumed responsibility for these registries.

b. Sequelae of POWs are both physical and psychological; however, physical sequelae have been more prevalent in the Japanese and Korean POWs than in the European POWs. Parasitic disease, tuberculosis, cardiovascular-renal disease, gastrointestinal and liver disease, as well as neurological and psychiatric disorders, have all been major causes of disability. Respiratory and neurological conditions are of particular interest among IRQ and AFG Veterans.

2. **Autopsy.** When an autopsy is performed on a former POW or Veteran eligible for inclusion in the special war-related Registries, in the interest of research, historical prospective, and to garner critical information to facilitate improved care for Veterans, the submission of autopsy tissues and reports for inclusion in the special Registries is strongly encouraged. Autopsies performed on former POWs, AGO, KUW, IRQ, and AFG Veterans must be performed in accordance with the all policies as outlined in paragraph 16, Post-Mortem Examination, and the local autopsy protocol. Prior to the submission of autopsy tissue and reports for inclusion in a special Registry, an additional consent must also be obtained to approve the inclusion of the autopsy in a special registry for research purposes.

a. In addition to the routine autopsy procedures, a morphologic study should be made of tissue samples from:

(1) Peripheral nerve (e.g., sciatic), skeletal muscle (e.g., psoas), and dorsal root ganglia (may be harvested with adjacent psoas muscle);

(2) Spinal cord at several levels including cervical widening;

(3) Medulla at the level of the hypoglossal nucleus;

(4) Pons;

(5) Cerebellum, to include the superior vermis and deep nuclei;

- (6) Midbrain;
 - (7) Hypothalamus, including mammillary bodies and wall of the third ventricle;
 - (8) Thalamus;
 - (9) Hippocampus, (at the level of the lateral geniculate body);
 - (10) Optic nerves;
 - (11) Rostral corpus callosum/cingulate gyrus;
 - (12) Cortex from each cerebral lobe, (the occipital lobe section should represent the visual/calcarine cortex); and
 - (13) Pituitary gland.
- b. The JPC will perform gross and microscopic examination of formalin-fixed brain, spinal cord, peripheral nerve and skeletal muscle at no charge to the contributing VA medical facility. A JPC consultation form should accompany the formalin-fixed tissue. Shipping and packaging instructions are the same as those for non-Registry VA autopsy brain specimens. The contributor will receive a JPC consultation report in such cases, issued by JPC Neuropathology.
- c. Further recommendations include taking specimens from the testes, prostate, bladder, and kidney.
- (1) Half of each testis.
 - (2) Material from the prostate should to include the capsule and the urethra. The sample should include as much of the gland as is practical and any focal lesions.
 - (3) Sections from the bladder should include any obvious lesions. If none, the sample should include the trigone.
 - (4) Sections from the kidney should include cortex and pelvis.
- d. Lung sections should include: one peripheral section from each lobe, preferably after one lung is inflated. It is helpful to record postmortem lung weights and to sample any palpable or visible focal lesions; this includes those of the parietal pleura and diaphragm. At least one section should include a medium sized bronchus, and one a mediastinal lymph node.
- e. Most importantly, attention should be directed toward the search for and identification of unexpected diseases and disorders.

NOTE: *Familiarity with the spectrum of diseases likely to affect former POWs enables the pathologist to render a more complete medical assessment of patients in this select group.*

3. All pathological material from POWs must be examined and reported in the customary manner at each medical center. A duplicate set of slides, blocks, and representative wet tissue is to be forwarded to the JPC, along with a copy of the contributor's autopsy report.
4. The JPC Registry Submission, Acknowledgement and Receipt Form, JPC Form 543 should be completed in its entirety and sent with the case materials submitted to the registries. It will be faxed back to the submitting VA medical facility, acknowledging the receipt of materials and indicating the JPC accession number. The JPC Form 543 form, along with instructions is available at www.jpc.capmed.mil, click on "Consultation." If tissue is submitted for consultation, (e.g., brain), a JPC Consultation Form must be completed and submitted with the specimen.

GUIDANCE FOR REQUESTING AN AUTOPSY

1. Autopsies are an integral component of the learning process for physicians. Autopsies are also essential for pathology training, providing important information for families of the deceased, and may be used for garnering critical information on former Prisoners of War (POW) or Veteran Special Registries to facilitate improved care for Veterans. Veterans Health Administration (VHA) staff are encouraged to help increase the autopsy rate by clear, thoughtful communication with patients and their families.
2. The Director of the Department of Veterans Affairs (VA) facility is responsible for ensuring that permission to perform an autopsy is requested from the surviving spouse or next of kin in every instance when a patient dies while an inpatient at a VA facility or under the immediate care of a VA facility and that consent to autopsy is obtained in advance and according to the policy outlined in VHA Handbook 1601B.04, Descendent Affairs and terms of Title 38 Code of Federal Regulations (CFR) 17.170. **NOTE:** *In making these requests, clinicians need to take into consideration any special medical or prior military service-related conditions, the need for accuracy of the death certificate, immediate and long-term contributions to medical knowledge, and the value of findings to the surviving spouse or the next of kin.*
3. When consent for an autopsy is obtained on a former POW or Veteran eligible for inclusion in a special war-related Registry, an effort should be made to obtain additional consent for inclusion of the autopsy tissues and report in the special registry. An additional consent which covers research purposes must be obtained prior to the taking of any specimens for such purpose and inclusion of the autopsy results in a special registry.
4. Documentation of the request for autopsy is included in the patient's medical record. This documentation must include notation of the participants in the discussion and whether the permission was granted or denied. When permission is denied, the reasons for the denial are to be recorded in the medical record. **NOTE:** *Under certain circumstances, detailed in 38 CFR 17.170, the Medical facility director may order an autopsy to be performed based on the implied consent of the decedent's surviving spouse or next of kin.*
5. Results of the autopsy are to be provided by the patient's primary or principal care provider to the surviving spouse or next-of-kin who consented to the post-mortem examination. Whenever possible, that provider should provide the result both orally and in writing. In all cases, disclosure of results must be done in a manner consistent with applicable information disclosure and privacy laws.
6. In all cases, requests are to be sensitive to the needs and wishes of the family. Patient education materials may be useful for family and others to help understand reasons for performing an autopsy. **NOTE:** *A suggested example is "Autopsy: Aiding the Living by Understanding Death" prepared by the College of American Pathologists Autopsy Committee in cooperation with the Armed Forces Institute of Pathology,*

Washington, DC. This pamphlet is published by the College of American Pathologists, 325 Waukegan Road, Northfield, IL 60093-2750.

7. The family is provided with the opportunity to ask questions.
8. The following information is to be conveyed at the time of each autopsy request so the family can make an informed decision. Become familiar with these topics so that they can be presented in a professional manner. A suggested presentation follows:
 - a. "I would like to talk with you about a postmortem examination, or autopsy. This can be a very distressing time, and often the procedure is poorly understood. I would appreciate your allowing me to explain a few important points regarding an autopsy so that I have done my job in assuring that you are able to make a well informed decision. Then we will certainly abide by whatever decision you make."
 - b. An autopsy or post-mortem examination is a careful, surgical procedure. Careful incisions are made; organs are removed for examination and tissue sampling. The incision is sewn back together. This is not a disfiguring procedure, and an open casket wake may be held if so desired.
 - c. An autopsy is provided by the VA as a courtesy to the family. There is no charge for this service.
 - d. Physicians learn considerable, important information from an autopsy. At autopsy, about 25 percent of the time we find conditions or disease we did not expect. This helps us become better physicians.
 - e. An autopsy is the last opportunity for the family to have their questions answered. Family members often have questions later, which they did not think of during the emotional period surrounding the death of their loved one. We are much more likely to be able to answer questions with the information available from an autopsy.
 - f. An autopsy may provide information which will help someone else. Because we can learn so much from autopsies and we often discover unexpected findings, physicians may identify ways to improve patient care or treat diseases more effectively.
 - g. Findings may be made which are important to surviving family members. Conditions or diseases which were not apparent before the time of death may be identified at autopsy. Infectious diseases such as tuberculosis or hereditary conditions may be discovered. Such findings can have important health implications for the family.
 - h. Provide the family opportunity to ask questions.

VA PERSONNEL REQUIREMENTS BY TEST COMPLEXITY

The requirements in this appendix have been determined by compiling the most restrictive requirements from the Federal Regulations, Title 42 Code of Federal Regulations (CFR) PART 493 Subpart M--Personnel for Non-Waived Testing, this Handbook, and The Joint Commission and College of American Pathologists (CAP) personnel requirements.

1. WAIVED TESTING:

a. **Laboratory Director.** The laboratory director is responsible for the overall operation and administration of the laboratory. The laboratory director must meet one of the following:

(1) Pathologist, with a current medical license, board certified in anatomic pathology and/or clinical pathology by the American Board of Pathology; or

NOTE: *Exceptions-when a pathologist cannot be recruited to serve as the laboratory director the following may be considered with approval by the local Chief or Director P&LMS and the National Enforcement Officer:*

(2) MD or DO with current medical license; or

(3) Ph.D. in chemical, physical or biological science.

b. **Ancillary Testing Coordinator.** Provides technical oversight for VA ancillary testing sites. The ancillary testing coordinator must be a certified medical technologist/medical laboratory scientist with training in the appropriate areas of laboratory testing.

c. **Testing Personnel.** The laboratory director must ensure that waived testing personnel:

(1) Meet facility defined minimum requirements; and

(2) Meet accreditation requirements; and

(3) Have documented training; and

(4) Successfully complete annual competency.

2. PROVIDER PERFORMED MICROSCOPY (PPM):

a. **Laboratory Director.** The laboratory director is responsible for the overall operation and administration of the laboratory. The laboratory director must meet one of the following:

(1) Pathologist, with a current medical license, board certified in anatomic pathology and/or clinical pathology by the American Board of Pathology; or

NOTE: *Exception-when a pathologist cannot be recruited to serve as the laboratory director the following may be considered with approval by the local Chief or Director P&LMS and the National Enforcement Officer:*

(2) MD or DO with current medical license.

b. **Ancillary Testing Coordinator.** Provides technical oversight for VA ancillary testing sites. The ancillary testing coordinator must be a certified medical technologist/medical laboratory scientist with training in the appropriate areas of laboratory testing.

c. **Testing Personnel.** Personnel must have current license, be privileged for each PPM test they perform, AND have one of the following credentials:

(1) MD, DO, or DPM; or

(2) Nurse Midwife; or

(3) Nurse Practitioner; or

(4) Physician Assistant; or

(5) Dentist.

3. MODERATE COMPLEXITY TESTING:

a. **Laboratory Director.** The laboratory director is responsible for the overall operation and administration of the laboratory. The laboratory director must meet one of the following:

(1) Pathologist, board certified in anatomic pathology and/or clinical pathology by the American Board of Pathology with a current medical license; or

(2) Ph.D. When a pathologist cannot be successfully recruited to serve as a laboratory director at a CBOC, specialty laboratory, ancillary testing site, or a very small or remotely located VA medical facility, a Ph.D. meeting the following may be considered with approval by the local Chief or Director, P&LMS and the National Enforcement Officer:

(a) Ph.D. in chemical, physical, biological, or clinical laboratory science; and

1. Board certification by an HHS approved board; or

2. 1 year experience directing or supervising non-waived testing.

(b) A non-pathologist laboratory director must be aligned under the oversight of a VA pathologist who serves in the P&LMS service-line (e.g. aligned under a Chief or Director, P&LMS at a VA medical facility or under a pathologist service-line Chief or Director at the VISN level).

NOTE: *A doctoral scientist may not serve as the laboratory director for a testing site that performs blood bank, transfusion medicine, or anatomic pathology testing except when the services of a consulting pathologist are retained.*

(3) **MD or DO (General Laboratory).** In a very small or remotely located VA medical facility, or in any VA medical facility where a pathologist cannot be successfully recruited, or there is not enough histology, cytopathology, or clinical pathology workload to justify a full-time or part-time pathologist in the laboratory, a non-pathologist physician may serve as the laboratory director. The laboratory director must meet the following:

(a) MD or DO with current medical license; and

1. 1 year experience directing or supervising non-waived testing; or
2. Beginning September 1, 1993, have at least 20 continuing medical education (CME) credit hours in laboratory practice commensurate with the director responsibilities defined in 42 CFR 493.1407; or
3. Equivalent laboratory training (20 CME credit hours) obtained during medical residency (For example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine).

(b) When a non-pathologist serves as the laboratory director, the services of a board-certified, qualified, licensed consulting pathologist must be retained to fulfill the CLIA defined laboratory technical functions.

(c) A non-pathologist laboratory director must be aligned under the oversight of a VA pathologist who serves in the P&LMS service-line (e.g. aligned under a Chief or Director, P&LMS at a VA medical facility or under a pathologist service-line Chief or Director at the VISN level) and must be approved by the National Enforcement Officer.

(4) **MD or DO Director of a Specialty Laboratory.** When a pathologist cannot be recruited to serve as the laboratory director, an MD or DO meeting the following may serve as the laboratory director of a specialty laboratory with approval by the local Chief or Director, P&LMS and the National Enforcement Officer:

(a) MD or DO with current medical license; and

1. 1 year experience directing or supervising non-waived testing; or
2. Beginning September 1, 1993, have at least 20 continuing medical education (CME) credit hours in laboratory practice commensurate with the director responsibilities defined in 42 CFR 493.1407; or

3. Equivalent laboratory training (20 CME credit hours) obtained during medical residency (For example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine).

(b) A non-pathologist laboratory director must be aligned under the oversight of a VA pathologist who serves in the P&LMS service-line (e.g. aligned under a Chief or Director, P&LMS at a VA medical facility or under a pathologist service-line Chief or Director at the VISN level).

NOTE: *Specialty laboratories directed by a non-pathologist laboratory director may not perform blood bank, transfusion medicine, or anatomic pathology activities on site except when the services of a consulting pathologist are retained.*

Exception: *CAP accredited laboratories with a total annual test volume exceeding 500,000 tests (including waived and moderate complex testing) must be directed by an individual who meets the high complexity laboratory director qualifications.*

b. **Technical Consultant.** Must be qualified by education and either training or experience to provide technical consultation for each of the specialties and subspecialties of service in which the laboratory performs testing. The technical consultant must meet one of the following:

(1) Pathologist, with a current medical license, board certified in anatomic pathology and/or clinical pathology by the American Board of Pathology; or

(2) MD or DO with current medical license; and

(a) At least 1 year of laboratory training during medical residency in the designated specialty or subspecialty for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or

(b) At least 2 years of experience directing or supervising high complexity testing in the designated specialty or subspecialty for which the technical consultant is responsible; or

(3) Ph.D. in chemical, physical or biological science and board certification by an HHS approved board.

NOTE: *A laboratory director meeting the moderate complexity technical consultant requirements above may serve concurrently as the technical consultant.*

NOTE: *Exception – If the lab director meets the moderate complexity technical consultant requirements above, then the lab director may designate the technical consultant functions to an individual who meets one of the following:*

(4) MD or DO with current medical license and at least 1 year of laboratory training or experience, in non-waived testing, in the designated specialty or subspecialty for which the technical consultant is responsible; or

(5) Ph.D. in chemical, physical or biological science with at least 1 year of laboratory training or experience, in non-waived testing, in the designated specialty or subspecialty for which the technical consultant is responsible.

(6) A bachelor's degree in a chemical, physical or biological science, medical technology, or clinical laboratory science from an accredited institution and have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty for which the technical consultant is responsible.

c. **Clinical Consultant.** Must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment, and management of patient care. The clinical consultant must meet the following:

(1) Pathologist, with a current medical license, board certified in anatomic pathology and/or clinical pathology by the American Board of Pathology; or

(2) MD or DO with current medical license; or

(3) Ph.D. in chemical, physical or biological science with board certification by an HHS approved board in the designated specialty for which the clinical consultant is responsible.

NOTE: A laboratory director meeting the requirements for clinical consultant outlined in this section may serve concurrently as the clinical consultant

d. **Testing Personnel.** All personnel performing moderate complexity testing must meet one of the following:

(1) MD, DO, or DPM with current medical license; or

(2) A doctoral, master's, or bachelor's degree in a chemical, physical, biological, clinical laboratory science, or medical technology from an accredited institution; or

(3) An associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or

(4) A high school diploma or equivalent and successful completion of an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or

(5) Have earned a high school diploma or equivalent; and have documentation of training appropriate for the testing performed prior to analyzing patient specimens.

Training must be provided to ensure that, at minimum, the individual has achieved each of the following skills:

- (a) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation, and storage of specimens;
- (b) The skills required for implementing all standard laboratory procedures;
- (c) The skills required for performing each test method and for proper instrument use;
- (d) The skills required for performing preventive maintenance, troubleshooting and calibration procedures related to each test performed;
- (e) A working knowledge of reagent stability and storage;
- (f) The skills required to implement the quality control policies and procedures of the laboratory;
- (g) An awareness of the factors that influence test results; and
- (h) The skills required to assess and verify the validity of patient test results through the evaluation of quality control sample values prior to reporting patient test results.

5. HIGH COMPLEXITY TESTING:

a. **Laboratory Director.** The laboratory director is responsible for the overall operation and administration of the laboratory. The laboratory director must meet one of the following:

(1) **Pathologist**, board certified in anatomic pathology and/or clinical pathology by the American Board of Pathology with a current medical license; or

(2) **Ph.D.** When a pathologist cannot be successfully recruited to serve as a laboratory director at a CBOC, specialty laboratory, ancillary testing site, or a very small or remotely located VA medical facility, a Ph.D. meeting the following may be considered with approval by the local Chief or Director, P&LMS and the National Enforcement Officer:

- (a) Ph.D. in chemical, physical or biological science; AND
- (b) Board certification by an HHS approved board.

(c) A non-pathologist laboratory director must be aligned under the oversight of a VA pathologist who serves in the P&LMS service-line (e.g. aligned under a Chief or Director, P&LMS at a VA medical facility or under a pathologist service-line Chief or Director at the VISN level). **NOTE:** *A doctoral scientist may not serve as the laboratory*

director for a testing site that performs blood bank, transfusion medicine, or anatomic pathology testing except when the services of a consulting pathologist are retained.

(3) **MD or DO (General Laboratory).** In a very small or remotely located VA medical facility, or in any VA medical facility where a pathologist cannot be successfully recruited, or there is not enough histology, cytopathology, or clinical pathology workload to justify a full-time or part-time pathologist in the laboratory, a non-pathologist physician may serve as the laboratory director. The laboratory director must meet the following:

(a) MD or DO with current medical license; AND

1. One year of laboratory training during medical residency in the designated specialty or subspecialty for which the laboratory director is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or

2. At least 2 years of experience directing or supervising high complexity testing in the designated specialty or subspecialty for which the laboratory director is responsible;

(b) When a non-pathologist serves as the laboratory director, the services of a board-certified, qualified, licensed consulting pathologist must be retained to fulfill the CLIA defined laboratory technical functions.

(c) A non-pathologist laboratory director must be aligned under the oversight of a VA pathologist who serves in the P&LMS service-line (e.g. aligned under a Chief or Director, P&LMS at a VA medical facility or under a pathologist service-line Chief or Director at the VISN level) and must be approved by the National Enforcement Officer.

(4) **MD or DO Director of a Specialty Laboratory.** When a pathologist cannot be recruited to serve as the laboratory director, an MD or DO meeting the following may serve as the laboratory director of a specialty laboratory with approval by the local Chief or Director, P&LMS and the National Enforcement Officer:

(a) MD or DO with current medical license; AND

1. One year of laboratory training during medical residency in the designated specialty or subspecialty for which the laboratory director is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or

2. At least 2 years of experience directing or supervising high complexity testing in the designated specialty or subspecialty for which the laboratory director is responsible.

(b) A non-pathologist laboratory director must be aligned under the oversight of a VA pathologist who serves in the P&LMS service-line (e.g. aligned under a Chief or Director, P&LMS at a VA medical facility or under a pathologist service-line Chief or Director at the VISN level). **NOTE:** *Specialty laboratories directed by a non-pathologist laboratory director may not perform blood bank, transfusion medicine or anatomic*

pathology activities on site except when the services of a consulting pathologist are retained.

b. **Technical Supervisor.** Must be qualified by education and either training or experience to provide technical consultation for each of the specialties and subspecialties of service in which the laboratory performs testing. The technical supervisor must meet one of the following:

(1) **For All Subspecialties except Histocompatibility and Cytogenetics.** A pathologist, with a current medical license, board certified in BOTH anatomic pathology AND clinical pathology by the American Board of Pathology; or

(2) **For the Subspecialties of Bacteriology, Mycobacteriology, Mycology, Virology and Parasitology.**

(a) Pathologist, with a current medical license, board certified in clinical pathology by the American Board of Pathology; or

(b) Licensed MD or DO with 1 year training or experience in high complexity microbiology with at least 6 months in the appropriate subspecialty; or

(c) Doctoral degree in chemical, physical, biological, clinical laboratory science, or medical technology from an accredited institution with 1 year training or experience in high complexity microbiology including a minimum of 6 months in the appropriate subspecialty; or

(d) Master's degree in chemical, physical, biological, clinical laboratory science, or medical technology from an accredited institution with 2 years training or experience in high complexity microbiology, including a minimum of 6 months in the appropriate subspecialty; or

(e) Bachelor's degree in laboratory science and in chemical, physical, biological, clinical laboratory science, or medical technology from an accredited institution with 4 years training or experience in high complexity microbiology, including a minimum of 6 months in the appropriate subspecialty; or

(3) **For the Specialties of Diagnostic Immunology, Chemistry, Hematology, and Radiobioassay.**

(a) Pathologist, with a current medical license, board certified in clinical pathology by the American Board of Pathology; or

(b) Licensed MD or DO with 1 year training or experience in high complexity testing in the appropriate specialty; or

(c) Doctoral degree in chemical, physical, biological, clinical laboratory science, or medical technology from an accredited institution with 1 year training or experience in high complexity testing in the appropriate specialty; or

(d) Master's degree in chemical, physical, biological, clinical laboratory science, or medical technology from an accredited institution with 2 years training or experience in high complexity testing in the appropriate specialty; or

(e) Bachelor's degree in laboratory science and in chemical, physical, biological, clinical laboratory science, or medical technology from an accredited institution with 4 years training or experience in high complexity testing in the appropriate specialty.

(4) For the Specialty of Immunohematology.

(a) Pathologist, with a current medical license, board certified in clinical pathology by the American Board of Pathology; or

(b) Licensed MD or DO with 1 year training or experience in high complexity testing in the specialty of immunohematology.

(5) For the Specialties of Histopathology and Cytopathology. A pathologist, with a current medical license, board certified in anatomic pathology by the American Board of Pathology.

(6) For the Specialties of Histocompatibility or Cytogenetics, refer to the specific requirements for each specialty in federal regulations under 42 CFR 493.1449.

NOTE: *The laboratory director meeting the requirements of this section may serve concurrently as the technical consultant.*

c. **Clinical Consultant.** Must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. The clinical consultant must meet one of the following:

(1) Be a pathologist, with a current medical license, board certified in anatomic pathology and/or clinical pathology by the American Board of Pathology; or

(2) For a specialty laboratory, is an MD or DO with current medical license and experience in the designated specialty or subspecialty for which the clinical consultant is responsible.

NOTE: *The laboratory director meeting the requirements of this section may serve concurrently as the technical consultant.*

d. **General Supervisor.**

(1) Qualify as a laboratory director for high complexity testing; or

(2) Qualify as a Technical Supervisor for high complexity testing; or

(3) Have and MD, DO, or doctorate, master's or bachelor's degree in chemical, physical, biological, clinical laboratory science, or medical technology from an accredited institution with 1 year lab training/experience in high complexity testing; or

(4) Have an associate degree in laboratory science or medical laboratory technology and 2 years lab training/experience in high complexity testing; or

(5) Previously qualified or could have qualified as general supervisor under federal regulations on or before February 28, 1992 (42 CFR 493.1462); or

(6) Passed the HHS exam for technologist between March 1, 1986 and December 31, 1987 and prior to January 1, 1994, met the requirements of a general supervisor in effect before February 28, 1992; or

(7) Prior to September 1, 1992, served as general supervisor of high complexity testing; and

(a) Prior to April 24, 1995 graduated from an accredited medical laboratory training program; or

(b) A high school graduate or equivalent and have completed a 50 week military program of Medical Laboratory Specialist; or

(c) Two years clinical laboratory training/experience in high complexity testing; or

(8) Prior to September 1, 1992 served as a general laboratory supervisor of high complexity testing, and high school graduate or equivalent, and 10 years of laboratory training/experience in high complexity testing, including 6 years supervisory experience between Sept 1, 1982 and Sept 1, 1992.

(9) **For Blood Gases:** If not qualified above,

(a) Bachelor's degree in respiratory therapy or cardiovascular technology and 1 year training/experience in blood gas analysis; or

(b) Associate degree in pulmonary function and 2 years training/experience in blood gas analysis.

NOTE: For information for General Supervisor qualifications for cytology, see 42 CFR 493.1469.

d. **Testing Personnel.** Personnel must meet one of one of the following:

(1) MD, DO, or DPM with current medical license; or

(2) A doctoral, master's, or bachelor's degree in a chemical, physical, biological, clinical laboratory science, or medical technology from an accredited institution; or

(3) An associate degree in a laboratory science or medical laboratory technology from an accredited institution; or

(4) Have education and training equivalent associate degree in a laboratory science, that includes:

(a) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either 24 semester hours of medical laboratory technology courses; or 24 semester hours of science courses (6 hours of chemistry, 6 hours of biology; and 12 semester hours of chemistry, biology, or medical laboratory technology in any combination; AND

(b) Have laboratory training that includes either completion of a clinical laboratory training program approved or accredited by the Accrediting Bureau of Health Education Schools (ABHES), the Committee on Allied Health Education and Accreditation (CAHEA), or other organization approved by HHS which may be included in the 60 semester hours specified above or at least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing.

NOTE: *Anyone hired after April 24, 1995 must have an associate's degree or equivalent in clinical laboratory science.*