

## PATHOLOGY AND LABORATORY MEDICINE SERVICE

### 1. SUMMARY OF MAJOR CHANGES: This directive:

a. Incorporates content from VHA Handbook 1106.01, Pathology and Laboratory Medicine Service (P&LMS) Procedures, dated January 29, 2016 (see paragraphs 3 through 16).

b. Updates responsibilities for the Under Secretary for Health; Assistant Under Secretary for Health for Operations; Executive Director, Pathology and Laboratory Medicine Service (PLM); PLM National Enforcement Officer; Veterans Integrated Services Network Director; Department of Veterans Affairs (VA) medical facility Director and VA medical facility Chief, PLM (see paragraph 2).

c. Adds responsibilities for Assistant Under Secretary for Health for Clinical Services/Chief Medical Officer; Associate Deputy Under Secretary for Health for Oversight, Risk and Ethics; Executive Director, VHA Diagnostic Services; Deputy National Director, PLM; Chair, National PLM Quality and Compliance Officer; National PLM Quality and Compliance Agent; VA medical facility Chief of Staff; VA medical facility Clinical Laboratory Improvement Amendments Laboratory Director; VA medical facility Administrative Laboratory Chief; VA medical facility Transfusion Medical Director; Chair, Blood and Blood Transfusion Utilization Review Committee; VA medical facility Pathology Physician; VA medical facility Ancillary Testing Coordinator; VA medical facility testing personnel; VA medical facility Safety Officer and VA medical facility Laboratory Biosafety Officer (see paragraph 2).

**2. RELATED ISSUES:** VHA Directive 1088, Communicating Test Results to Providers and Patients, dated July 11, 2023; VHA Directive 1101.12, Mohs Micrographic Surgery, dated January 27, 2023; VHA Directive 1131, Management of Infectious Diseases and Infection Prevention and Control Programs, dated November 27, 2023; VHA Directive 1138, Patient Self-Testing for Monitoring of Prothrombin Time International Normalized Ratio in Patients on Warfarin Anticoagulation Therapy, dated January 27, 2023; and VHA Directive 1601B.04, Decedent Affairs, dated December 1, 2017.

**3. POLICY OWNER:** The Office of Pathology and Laboratory Medicine Service (11DIAG2) is responsible for the content of this directive. Questions may be referred to [VHAPLMSPProgramOffice@va.gov](mailto:VHAPLMSPProgramOffice@va.gov).

**4. RESCISSIONS:** VHA Directive 1106, Pathology and Laboratory Medicine Service, dated July 27, 2018; VHA Handbook 1106.01, Pathology and Laboratory Medicine Service (P&LMS) Procedures, dated January 29, 2016; and VHA Directive 1186, Transfusion Verification and Identification Requirements, dated June 21, 2017, are rescinded.

**5. RECERTIFICATION:** This Veterans Health Administration (VHA) directive is scheduled for recertification on or before the last working day of January 2029. This VHA directive will continue to serve as national VHA policy until it is recertified or rescinded.

**6. IMPLEMENTATION SCHEDULE:** This directive is effective upon publication.

**BY DIRECTION OF THE OFFICE OF THE  
UNDER SECRETARY FOR HEALTH:**

/s/ Erica M. Scavella, MD, FACP, FACHE  
Assistant Under Secretary for Health  
for Clinical Services/CMO

**NOTE:** *All references herein to VA and VHA documents incorporate by reference subsequent VA and VHA documents on the same or similar subject matter.*

**DISTRIBUTION:** Emailed to the VHA Publications Distribution List on January 29, 2024.

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## PATHOLOGY AND LABORATORY MEDICINE SERVICE

### 1. POLICY

This Veterans Health Administration (VHA) directive states authority and policy for the administrative structure and management of services and service lines providing laboratory testing to Department of Veterans Affairs (VA) medical facilities, their outreach functions and ancillary testing sites. This directive also defines laboratory testing requirements unique to VA. **AUTHORITY:** P.L. 100-578, P.L. 102-139, 38 C.F.R. § 17.3500 and 42 C.F.R. part 493.

### 2. RESPONSIBILITIES

a. **Under Secretary for Health.** The Under Secretary for Health is responsible for:

(1) Ensuring overall VHA compliance with this directive.

(2) Ensuring that VHA retains exclusive oversight and enforcement responsibilities for Pathology and Laboratory Medicine Service (PLM).

(3) On appeal through recognized organizational channels, sustaining, remanding or rejecting the Clinical Laboratory Improvement Amendments (CLIA) certification decisions by the National PLM Quality and Compliance Officer.

b. **Assistant Under Secretary for Health for Clinical Services/Chief Medical Officer.** The Assistant Under Secretary for Health for Clinical Services/Chief Medical Officer is responsible for:

(1) Supporting the Executive Director, VHA Diagnostic Services with implementation and oversight of this directive.

(2) Providing resources for the operation and conduct of National PLM Program Office responsibilities.

c. **Associate Deputy Under Secretary for Health for Oversight, Risk and Ethics.** The Associate Deputy Under Secretary for Health for Oversight, Risk and Ethics is responsible for:

(1) Providing review of National PLM Program Office quality, compliance and safety aggregated national data and metrics, submitted upon request by the PLM National Enforcement Office (NEO).

(2) Providing guidance to NEO based on the results of aggregated data reviews.

(3) Serving as an additional report for any concerns by PLM NEO and taking appropriate action when requested by the National PLM Quality and Compliance Officer.

(4) Ensuring independent oversight of Veterans Integrated Service Networks (VISN) and VA medical facility-based VHA PLM clinical services by PLM NEO.

d. **Assistant Under Secretary for Health for Operations.** The Assistant Under Secretary for Health for Operations is responsible for:

(1) Communicating the contents of this directive to each of the VISNs.

(2) Assisting VISN Directors to resolve implementation and compliance challenges in all VA medical facilities within that VISN.

(3) Providing oversight of VISNs to ensure compliance with this directive and its effectiveness.

e. **Executive Director, VHA Diagnostic Services.** The Executive Director, VHA Diagnostic Services is responsible for:

(1) Supporting the Executive Director, PLM with policy development and oversight of this directive.

(2) Supporting VISN Directors with implementation and compliance with this directive.

f. **Executive Director, Pathology and Laboratory Medicine Service.** The Executive Director, PLM is responsible for:

(1) Coordinating a nationwide contract or alternate method for accreditation or compliance verification by a VA-approved laboratory accreditation or compliance agency and for proficiency testing (PT) procurement in collaboration with the National PLM Quality and Compliance Officer. ***NOTE: For additional information about accreditation and compliance verification, see paragraph 5.***

(2) Ensuring this directive is implemented in compliance with 42 C.F.R. part 493 and is consistent with 38 C.F.R. § 17.3500.

(3) Providing guidance and recommendations to VHA senior leadership for the establishment of VHA national policies applicable to VA medical facilities performing patient laboratory testing.

(4) Providing PLM guidance to VHA senior leadership and the VA medical facility laboratory community to ensure that timely, cost effective and high-quality anatomic and clinical pathology services are provided to VA patients.

(5) Providing oversight and enforcement of this directive in conjunction with the National PLM Quality and Compliance Officer.

(6) Overseeing the quality of services provided by VA medical facility laboratories as well as laboratory compliance with regulatory, accreditation and policy guidelines.

(7) Ensuring that VA medical facility laboratories and testing sites are appropriately accredited or their compliance is verified by a VA-approved accrediting agency or compliance agency under the VA national contract or other method as outlined in this directive and that the required accreditation or compliance programs are fully implemented.

(8) Arranging and monitoring PT programs in VA medical facility laboratories consistent with 38 C.F.R. §§ 17.3500(g) and (h).

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

(10) Advising VISN Directors on problems and concerns related to the quality of the pathology and laboratory services provided and laboratory testing performed in VA medical facilities under their purview.

(11) Working with the National PLM Quality and Compliance Officer and the VA medical facility Chief, PLM at each VA medical facility to ensure that corrective action is implemented where potential for adverse patient outcome is identified.

(12) Initiating informational queries or surveys to track and analyze laboratory testing performance at VA medical facilities.

(13) For VA medical facility laboratories performing moderate or high complexity testing, ensuring that the VA medical facility Chief, PLM submits data and trend analysis of laboratory testing performed at the VA medical facility when informational queries or surveys are initiated.

(14) Reviewing and approving VA medical facility Chief, PLM appointments when the appointee possesses any exceptions to the position standards. **NOTE:** For information on VA medical facility Chief, PLM position requirements, see paragraph 3.

g. **Deputy National Director, Pathology and Laboratory Medicine Service.** The Deputy National Director, PLM is responsible for supporting the National Director, PLM in enforcing this directive.

h. **National Pathology and Laboratory Medicine Service Quality and Compliance Officer.** The National PLM Quality and Compliance Officer is responsible for:

(1) Ensuring that each VA medical facility CLIA Laboratory Director submits corrective actions for findings from accrediting and regulatory agency inspections or accreditation processes.

(2) Reviewing testing site registration requests to ensure that VA and Federal regulations and accreditations requirements for patient testing are met.

(3) Reviewing testing site registrations to ensure adherence to CLIA standards and issuing a CLIA number to testing sites that meet VA and Federal regulations and accreditation requirements.

(4) Providing oversight and enforcement of this directive in conjunction with the Executive Director, PLM.

(5) Working with the Executive Director, PLM and the VA medical facility Chief, PLM to ensure that corrective action is implemented where potential for adverse patient outcome is identified.

(6) Reporting to the Executive Director, PLM regarding issues of VHA CLIA compliance, proposing action plans and other mitigation strategies to VISN Directors and, as necessary, facilitating the provision of safe and high-quality PLM clinical services for VA patients.

(7) Making decisions in an independent manner, free of bias or external influence from standard operational chain-of-command for VA medical facilities.

(8) Reporting data and relevant metrics to the Associate Deputy Under Secretary for Health for Oversight, Risk and Ethics, ensuring parallel VHA leadership PLM quality review. This includes reporting, at least quarterly, aggregate national data regarding quality, safety, compliance and other data as defined by the Associate Deputy Under Secretary for Health for Oversight, Risk and Ethics and the Executive Director, PLM.

(9) Reporting directly to the Executive Director, Diagnostic Services and the Associate Deputy Under Secretary for Health for Oversight, Risk and Ethics any concerns of inappropriate external influence (e.g., media, lobbies, Congress) that might threaten the independent nature of regulatory CLIA oversight by PLM NEO.

(10) Assessing regulatory compliance and enforcement for VA medical facility laboratories for requirements defined in 42 C.F.R. part 493 and applied in 38 C.F.R. § 17.3500 and this directive, with the assistance of National PLM Quality and Compliance Agents and under the authority of PLM NEO.

(11) Utilizing organizational resources and collaborating with the Centers for Medicare & Medicaid Services (CMS), Department of Defense, United States (U.S.) Food and Drug Administration (FDA), various accrediting organizations and other Federal and civilian external agencies to ensure consistency in regulatory oversight.

(12) Providing supervision to National PLM Quality and Compliance Agents on VA medical facility laboratory enforcement.

(13) Directing the CLIA Program and ensuring that VA medical facility laboratories are registered with PLM NEO and are issued a CLIA number. **NOTE:** For additional information about the CLIA application process, see paragraph 4.

(14) Coordinating a nationwide contract or alternate method for accreditation or compliance verification by a VA-approved laboratory accreditation or compliance agency and for PT procurement in collaboration with the Executive Director, PLM.

**NOTE:** For additional information about accreditation and compliance verification, see paragraph 5.

(15) Providing guidance and education for performance improvement activities for VA medical facility laboratories to ensure conformance to requirements.

(16) Ensuring that VA medical facility laboratories within VA are accredited or have compliance verified by a VA-approved accrediting or compliance organization.

(17) Evaluating accrediting, compliance and regulatory agency summary reports submitted by National PLM Quality and Compliance Agents and VA-designated laboratory accrediting agencies and ensuring appropriate corrective action when issues are identified on the report.

(18) Ensuring that VA medical facility laboratories successfully participate in a CMS-approved PT program for each analyte and instrument or method.

(19) Initiating focused reviews of VA medical facility laboratories if indicated (e.g., by VISN or VA medical facility complaint or unsatisfactory PT results), implementing corrective action as necessary to ensure that a high standard of service and patient care is provided and approving resumption of laboratory testing when satisfactory improvement has been demonstrated.

(20) Ensuring the VA medical facility CLIA Laboratory Director is informed when patient testing must be suspended due to failure to perform tests on PT challenges within the time frame specified by the PT program. See paragraph 6.c. for more information.

(21) Developing the strategic plan for PLM NEO by incorporating goals, objectives, strategies and performance measures to track and measure the extent to which strategic objectives of VHA are met.

(22) Developing coordinated action plans to address data management and align key organizational activities to VA strategic objectives.

(23) Reviewing and approving VA medical facility CLIA Laboratory Director appointments at VA medical facility specialty laboratories when the appointee is not a pathology physician.

(24) Ensuring National PLM Quality and Compliance Agents complete on-site VA medical facility compliance audits.

(25) Performing quality reviews of the results of PT programs and preparing and submitting annual reports to the VA medical facility Chief, PLM, at each VA medical facility that provides anatomic pathology service.



(26) Overseeing the participation activities of each anatomic pathology service.

(27) Ensuring PLM NEO reviews and approves, as appropriate, blood donor activity for VA medical facilities that provide transfusion services.

(28) Investigating internal and external complaints regarding PLM services and adverse events and reviewing corrective action as needed.

(29) Identifying and facilitating actions related to immediate jeopardy and CLIA sanctions including suspension, limitation or revocation of CLIA numbers and monitoring corrective actions through to resolution.

i. **National PLM Quality and Compliance Agent.** The National PLM Quality and Compliance Agent is responsible for:

(1) Assisting the National PLM Quality and Compliance Officer in assessing regulatory compliance and enforcement for VA medical facility laboratories for requirements as defined in 42 C.F.R. part 493 and applied in 38 C.F.R. § 17.3500 and this directive.

(2) Enforcing VA medical facility laboratory matters under the supervision of the National PLM Quality and Compliance Officer.

(3) Conducting on-site VA medical facility compliance audits.

(4) Compiling accrediting, compliance and regulatory agency summary reports and submitting to the National PLM Quality and Compliance Officer.

j. **Veterans Integrated Services Network Director.** The VISN Director is responsible for:

(1) Ensuring that VA medical facility laboratories and VA health care providers performing laboratory testing, transfusion medicine and anatomic pathology comply with 42 C.F.R. part 493 and this directive.

(2) Ensuring that VA medical facility laboratories within the VISN meet the requirements for external PLM accreditation or compliance verification. For more information on accreditation and compliance verification, see paragraph 5.

(3) Communicating pathology and laboratory medicine management priorities and maintaining a mode for communication with the National PLM Program Office to ensure alignment and coordination with national priorities.

(4) Ensuring that VA medical facility action plans addressing PLM non-compliance with accreditation, VA regulations or regulatory requirements are implemented and completed.

(5) Ensuring each VA medical facility has the capability to perform autopsies either on-site or contracted to another VA medical facility or accredited community care facility.

k. **VA Medical Facility Director.** The VA medical facility Director is responsible for:

(1) Ensuring that the applicable requirements of 42 C.F.R. part 493 as applied in 38 C.F.R. § 17.3500, this directive and accrediting organizations are met when laboratory patient care services are offered by VA medical facility laboratories, regardless of the physical location of the laboratory or the service, or of the administrative structure assigned to direct the personnel or technical aspects of the testing site.

(2) Ensuring that the VA medical facility Chief, PLM leads the VA medical facility laboratory and is a qualified, licensed pathology physician who is a board-certified physician in anatomic pathology, clinical pathology or both by the American Board of Pathology.

(3) Ensuring that the VA medical facility Chief, PLM and VA medical facility CLIA Laboratory Director possess a broad knowledge of clinical medicine, basic medical sciences, clinical laboratory sciences and management operations and meet the appropriate qualifications of CLIA Laboratory Director or technical supervisor as outlined in 42 C.F.R. part 493, Subpart M as applied in C.F.R. § 17.3500(k).

(4) Ensuring that the VA medical facility Chief, PLM or VA medical facility CLIA Laboratory Director, is appointed as a voting member to the VA medical facility Clinical Executive Board or analogous medical staff committee and all other appropriate committees.

(5) Ensuring that testing sites that perform moderate or high complexity laboratory tests are inspected and accredited or compliance is verified by a VA-approved accrediting or compliance organization as outlined in paragraph 5 of this directive.

(6) Ensuring that testing sites performing only waived testing or provider-performed microscopy (PPM) procedures are inspected and accredited or compliance is verified as part of the main laboratory or hospital accreditation process.

(7) Ensuring that laboratory testing, regardless of complexity level or physical location, is performed under the oversight of the VA medical facility Chief, PLM including testing sites that may be under a separate VA medical facility CLIA Laboratory Director, CLIA registration number or accreditation. This includes ancillary testing sites.

(8) Ensuring that individuals performing laboratory testing meet the personnel requirements defined in 42 C.F.R. part 493 for the identified test complexity.

(9) Ensuring safe and adequate physical and environmental conditions of the VA medical facility laboratory for the activities being performed.

(10) Ensuring that laboratory testing within the VA medical facility, ancillary testing sites and outreach functions is performed under a current CLIA certificate of the appropriate complexity level for the laboratory test.

(11) Ensuring that VA medical facility PLM and ancillary testing sites successfully participate in a CMS-approved PT program. The VA medical facility laboratory PT program must meet the requirements of CLIA, the accrediting agency and VA for analytes for which PT is available, including waived, PPM and unregulated analytes as outlined in paragraph 6. For analytes for which no PT is available, an alternate method must be in place. **NOTE:** *For additional information about PT requirements, see paragraph 6.*

(12) Ensuring that the VA medical facility has a working Blood Transfusion Utilization Review Committee, a designated program that adheres to the mandates of this directive, and that there is a formalized comprehensive process to monitor transfusion-related activities.

(13) Appointing a Blood Transfusion Utilization Review Committee Chair who must be a physician with knowledge and experience in patient blood management principles. **NOTE:** *Patient blood management is a program that encompasses all aspects of patient evaluation and clinical management surrounding the transfusion decision-making process, including the application of appropriate indications, as well as minimization of blood loss and optimization of patient red cell mass.*

(14) Ensuring that the VA medical facility laboratory participates in the VA Laboratory Management Index Program and other information queries or surveys initiated by the Executive Director, PLM for the purpose of needs assessment or evaluation of the effectiveness of PLM.

(15) Ensuring that the VA medical facility Information Technology Office and Biomedical Services provide resources to laboratory information management for appropriate operator support, interface, training, hardware and backup procedures for computer downtime.

(16) Ensuring that permission to perform an autopsy (i.e., post-mortem examination) is requested by the VA medical facility in every instance when a patient dies while an inpatient at a VA medical facility or under the immediate care of a VA medical facility (e.g., during an outpatient or emergency care visit or ambulatory care procedure) and providing authorization as appropriate. **NOTE:** *For more information on post-mortem examination, see 38 C.F.R. § 17.170(b) and (c), VHA Directive 1601B.04, Decedent Affairs, dated December 1, 2017, and paragraph 16 of this directive.*

(17) In cases where the U.S. does not have exclusive jurisdiction over the area where the body was found, ensuring that the medical examiner or coroner in that area is informed and in all instances in which VA intends to transfer patient information to the coroner or medical examiner, requesting review by Office of Chief Counsel in the

Districts Counsel to ensure that authority exists in all applicable statutes in paragraph 16.a., before releasing the information. See paragraph 16 for more information.

(18) Ensuring that documentation of the request for autopsy is included in the patient's electronic health record (EHR). This documentation must include names of request discussion participants and whether permission was granted or denied. When permission is denied, the reasons for the denial must be recorded in EHR.

(19) Ensuring that autopsies on coroner and medical examiner cases that are performed at VA medical facilities have the concurrent permission of both the coroner or medical examiner and the surviving spouse or next-of-kin.

(20) Ensuring that restricted autopsy examinations (i.e., those limited to a specific area, such as brain and spinal cord, chest cavity or abdominal cavity) meet the requirements for autopsy.

(21) Ensuring that the results of autopsies are included in VA medical facility medical staff education and quality management programs. **NOTE:** *Findings from post-mortem examinations must be presented to medical staff at least once a year. For additional information about post-mortem requirements, see paragraph 16.*

(22) Ensuring autopsies in cases of infection with high-risk pathogens are performed using appropriate personal protective equipment, environmental controls and decontamination procedures commensurate with the biosafety precautions indicated for the known or suspected pathogen. **NOTE:** *VA medical facility procedures must be followed in the event the VA medical facility Chief, PLM cannot ensure or comply with appropriate biosafety precautions. For more information on infection control, see paragraph 9.*

(23) When a full-time or part-time pathology physician cannot be recruited to serve as the VA medical facility Chief, PLM or VA medical facility CLIA Laboratory Director, the VA medical facility Director is responsible for:

(a) Retaining the services of a qualified, licensed consulting pathology physician to serve as the VA medical facility contracted consulting pathology physician and fulfill the CLIA-defined laboratory technical functions as cited in 42 C.F.R. part 493, Subpart M.

(b) Appointing a qualified individual to serve as the VA medical facility Administrative Laboratory Chief to provide oversight and direction for laboratory functions and to provide direction for the technical functions provided by the VA medical facility contracted consulting pathology physician. **NOTE:** *When a consulting pathology physician is retained, the VA medical facility Administrative Laboratory Chief serves as the VA medical facility CLIA Laboratory Director and therefore must meet the laboratory director personnel qualifications for the appropriate laboratory complexity according to laboratory accreditation requirements, this directive and as outlined in the laboratory director personnel standards in 42 C.F.R. part 493, Subpart M as applied in C.F.R. § 17.3500(k).*

(c) Ensuring the VA medical facility contracted consulting pathology physician fulfills the technical functions as cited in 42 C.F.R. part 493 and this directive and is provided the appropriate resources to fulfill these requirements.

(d) Assigning the VA medical facility contracted consulting pathology physician as a member of the VA medical facility Clinical Executive Board or analogous medical staff committee and all other appropriate committees.

(e) Ensuring that the VA medical facility contracted consulting pathology physician has an active role in the educational and staff competency programs of the institution and VA medical facility laboratory.

(f) Ensuring that the VA medical facility contracted consulting pathology physician performs on-site visits as specified by their contract with the VA medical facility, consistent with the needs of the VA medical facility laboratory.

I. **VA Medical Facility Chief of Staff.** The VA medical facility Chief of Staff (CoS) is responsible for:

(1) Ensuring that the VA medical facility Chief, PLM is provided with an inventory of the location and type of ancillary testing equipment and ancillary testing sites, including bedside testing sites, methodology to be used and the estimated number of tests to be performed once a year.

(2) Ensuring VA medical facility pathology physicians and contract or fee-basis pathology physicians who are privileged in the areas of surgical pathology, cytopathology or bone marrow pathology have a minimal 10% random review of their cases as part of Focused Professional Practice Evaluations (FPPE) and Ongoing Professional Practice Evaluation (OPPE).

(3) Ensuring external reviews of FPPE and OPPE performed for VA medical facilities with one or two pathology physicians and Service or Section Chiefs are performed by a VA health care provider from another VA medical facility with similar specialized training and privileges as the pathology physician being evaluated.

(4) Ensuring that external reviews of FPPE and OPPE performed for VA medical facilities with one or two pathology physicians and Service or Section Chiefs are directly sent to the VA medical facility CoS.

(5) If Mohs surgery is performed on-site, ensuring that an ongoing 10% random retrospective second review is performed for Mohs surgeries. A retrospective second review must be performed for all Mohs surgeries cases for which a previous tissue diagnosis has not been performed by the local VA medical facility PLM. Refer to VHA Directive 1101.12, Mohs Micrographic Surgery, dated January 27, 2023, for more information.

(6) Ensuring that laboratory testing performed outside of the main VA medical facility laboratory is managed under the ancillary testing program under the oversight of the VA

medical facility Chief, PLM, including laboratory testing performed by VA health care providers (e.g., physicians, dentists, nurse practitioners, midwives, clinical pharmacists and physician assistants). **NOTE:** *This does not apply to reference laboratory testing.*

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

(8) Ensuring there is a mechanism in place to mandate that VA health care providers or testing sites identified by the VA medical facility Chief, PLM as failing to follow laboratory testing requirements are not allowed to continue performing laboratory tests on patients.

(9) In conjunction with the VA medical facility Chief, PLM, ensuring that there is an ongoing mechanism for monitoring and evaluating the usefulness and appropriateness of specialized testing requests to outside reference laboratories and ensuring that the testing is appropriate for patient care.

(10) When patients receive treatment at a VA medical facility based on tissue samples obtained off-site (i.e., at another VA medical facility or community care facility), ensuring that the patient's VA health care provider obtains and submits the outside tissue slides to the VA medical facility pathology physicians at the VA medical facility (or affiliated facility if no pathology service is available on-site) where the patient receives treatment so that the diagnosis can be confirmed. **NOTE:** *Treatments or procedures on the patient must not be performed until confirmation of the diagnosis has been obtained.*

(11) Providing overall management of post-mortem examination services that include:

(a) Forwarding autopsy examination authorization requests and consent from the surviving spouse or next-of-kin to the VA medical facility Director.

(b) Providing sufficient competent staff for the examinations.

(c) Maintaining suitable facilities and appropriate coordination with funeral directors and local authorities.

(12) Ensuring that post-mortem examination findings are used in the internal monitoring of the VA medical facility's medical practice. **NOTE:** *For additional information about post-mortem requirements, see paragraph 16.*

(13) Reviewing blood utilization review reports submitted by the Chair, Blood Transfusion Utilization Review Committee and taking corrective action if needed.

m. **VA Medical Facility Chief, Pathology and Laboratory Medicine Service.** The VA medical facility Chief, PLM is responsible for:

(1) If not also serving as the VA medical facility CLIA Laboratory Director, working with the VA medical facility CLIA Laboratory Director to support VA medical facility compliance with this directive.

(2) If also serving as the VA medical facility CLIA Laboratory Director, fulfilling all responsibilities of the VA medical facility CLIA Laboratory Director as outlined in paragraph 2.n.

(3) Serving as a voting member to the VA medical facility Clinical Executive Board or analogous medical staff committee and all other appropriate committees, if appointed by the VA medical facility Director. **NOTE:** *If the VA medical facility Chief, PLM and is not also serving as the VA medical facility CLIA Laboratory Director, the VA medical facility Director may assign this to the VA medical facility CLIA Laboratory Director.*

(4) Overseeing all laboratory testing performed at VA medical facility laboratories including, but not limited to, ancillary testing sites including overseeing the ancillary testing program (see paragraph 11), specialty laboratories, home-based healthcare (HBHC) testing sites and research laboratories performing clinical laboratory testing, regardless of complexity level.

(5) Serving as a consultant for specialty laboratories and ensuring that laboratory testing is carried out in compliance with 42 C.F.R. part 493 as applied in 38 C.F.R. § 17.35000. **NOTE:** *Testing must be overseen under the ancillary testing program.*

(6) Working with the Executive Director, PLM and the National PLM Quality and Compliance Officer to ensure that corrective action is implemented where potential for adverse patient outcome is identified.

(7) Directing and coordinating the patient care, administration, education and research functions of the VA medical facility PLM.

(8) Ensuring that quality patient services are provided to VA patients and that personnel operations and laboratory management are run efficiently and effectively.

(9) Providing consultation and guidance to VA health care providers regarding matters pertaining to pathology and laboratory medicine and the medical significance of laboratory findings.

(10) Designating, in writing, which VA health care providers are authorized to perform pathology consultations, including documenting medical diagnoses and information in the patient's EHR.

(11) Serving as or delegating a VA medical facility CLIA Laboratory Director as a voting member of the VA medical facility Clinical Executive Board or analogous medical staff committee and all other appropriate committees. **NOTE:** *If the VA medical facility*

*Chief, PLM does not serve as the VA medical facility CLIA Laboratory Director, they must ensure a VA medical facility CLIA Laboratory Director is appointed that meets the qualifications as listed in 42 C.F.R. part 493.*

(12) Participating in applicable cross-organizational performance-improvement activities, developing and communicating to the VA medical facility CoS objectives and coordinating efforts to integrate patient care and support services.

(13) Providing educational direction for the medical and laboratory staff and participating in VA medical facility educational programs as appropriate.

(14) Directing and coordinating the functions of the VA medical facility PLM and outreach functions based upon the mission, special needs and size of the VA medical facility.

(15) Ensuring that VA medical facility laboratories performing patient care testing meet requirements for hospital accreditation.

(16) Ensuring that the VA medical facility submits to annual registration and FDA inspection if the VA medical facility draws or prepares components for or provides transfusion services.

(17) Ensuring that, if the VA medical facility PLM has a blood bank or transfusion service, it maintains current Association for the Advancement of Blood & Biotherapies (AABB) accreditation.

(18) Acting as a consultant for the VA medical facility whenever a community care provider is contracted to perform laboratory testing for VA patients. The VA medical facility Chief, PLM must ensure that documentation is obtained to verify that the contracted laboratory is appropriately CLIA certified and, if it is a non-waived laboratory, accreditation is documented.

(19) Ensuring that VA-ordered laboratory test results are entered into the EHR.

(20) Reviewing aggregate data and trend analysis of laboratory testing performed at the VA medical facility. **NOTE:** *VA medical facility laboratories performing moderate or high complexity testing must participate in VA workload captures, informational queries or surveys initiated by the Executive Director, PLM.*

(21) Providing the guidance of post-mortem examinations, including in all instances where legal consent must be obtained prior to conducting a post-mortem examination and in a manner consistent with the terms of 38 C.F.R. § 17.170 and VHA Directive 1601B.04. **NOTE:** *For additional information about post-mortem requirements, see paragraph 16.*

(22) Ensuring OPPE of VA medical facility pathology physicians and all technical and quality aspects of anatomic pathology are met.



(23) Ensuring FPPEs are performed as appropriate. See paragraph 21.g. for more information.

(24) Overseeing all PLM-related quality reviews (e.g., OPPE, FPPE, the PLM QM Program, anatomic pathology internal quality review).

(25) Reviewing and approving VA medical facility CLIA Laboratory Director appointments at VA medical facility specialty laboratories when the appointee is not a pathology physician.

(26) Collaborating with and providing consultation to the service managing the patient self-testing program when a patient self-testing program is implemented. **NOTE:** *For more information on circumstances where consultation is warranted, see paragraph 11.d.*

(27) Ensuring that the laboratory tests are being performed in accordance with 42 C.F.R. part 493 and VHA policy. In concert with the VA medical facility CoS, the VA medical facility Chief, PLM must ensure that providers who fail to follow these testing requirements are not allowed to continue to perform testing.

(28) Overseeing the VA medical facility Administrative Laboratory Chief, for VA medical facilities that have this position.

(29) For VA medical facilities that perform anatomic pathology, ensuring there are procedures in place for third-party consultation processes to ensure quality patient care and eliminate conflicts of interest. For more information see paragraph 13.g.(4).

(30) Establishing criteria for rescreening cytopathology specimens for high-risk patients. See paragraph 13.d.

(31) Approving VA health care providers as competent to read Mohs surgery frozen sections. See paragraph 13.e.

(32) In conjunction with the VA medical facility CoS, ensuring that there is an ongoing mechanism for monitoring and evaluating the usefulness and appropriateness of specialized testing requests to outside reference laboratories and ensuring that the testing is appropriate for patient care.

n. **VA Medical Facility Clinical Laboratory Improvement Amendments Laboratory Director.** **NOTE:** *The VA medical facility CLIA 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. In many instances the VA medical facility Chief, PLM also fills the roll of VA medical facility CLIA Laboratory Director. The VA medical facility CLIA Laboratory Director must meet the personnel qualifications for the appropriate laboratory complexity according to laboratory accreditation requirements, this directive (paragraph 3.j.) and as outlined in the laboratory director personnel standards in 42 C.F.R. part 493, Subpart M. The CLIA Laboratory Director may delegate some responsibilities of this*

*directive to staff that meet the qualifications for positions listed in 42 C.F.R. part 493 Subpart M. However, laboratory director responsibilities specifically listed in 42 C.F.R part 493, Subpart M must not be delegated.* The VA medical facility CLIA Laboratory Director is responsible for:

(1) Working with the VA medical facility Chief, PLM to support VA medical facility compliance with this directive.

(2) Providing oversight for overall operation and administration of the VA medical facility laboratory, including ensuring that quality patient services are provided and that competent qualified personnel are employed.

(3) Serving as a voting member to the VA medical facility Clinical Executive Board or analogous medical staff committee and all other appropriate committees, if appointed by the VA medical facility Director. **NOTE:** *If the VA medical facility CLIA Laboratory Director is not also serving as the VA medical facility Chief, PLM, the VA medical facility Director may assign this to the VA medical facility Chief, PLM.*

(4) Submitting registration requests to PLM NEO to obtain a CLIA number.

(5) Ensuring that a sufficient number of appropriately educated, experienced and trained testing personnel are employed by the VA medical facility laboratory to provide appropriate consultation, properly supervise and accurately perform tests and report test results.

(6) Ensuring the physical and environmental conditions of the VA medical facility laboratory are adequate and appropriate for the testing performed, the environment for employees is safe from physical, chemical and biological hazards and safety and biohazard requirements are followed.

(7) Identifying laboratory testing performed within the VA medical facility and its outreach clinics regardless of the complexity or where the testing is performed within the organization and providing assistance and oversight to ensure that patient laboratory testing performed complies with 42 C.F.R. 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) Reviewing and approving new test procedures and ensuring trained personnel follow the approved procedures.

(9) Ensuring current accreditation by a VA-designated, CMS-approved accrediting organization of all testing sites that perform non-waived laboratory tests for patient care.

(10) Submitting corrective actions for findings from accrediting and regulatory agency inspections or accreditation processes to PLM NEO.

(11) Providing oversight to ancillary testing sites, including insurance of good laboratory practice.

(12) Designating a VA medical facility ancillary testing coordinator to monitor and oversee the ancillary testing sites and support the ancillary testing program.

(13) Ensuring that laboratory testing is performed by personnel that have been appropriately trained and deemed competent in accordance with qualifications in 42 C.F.R. part 493.

(14) Assuming responsibility for the implementation of the PLM quality management (QM) program, monitoring the ongoing effectiveness of a comprehensive continuous PLM QM plan and ensuring the PLM QM program is conducted consistent with 38 U.S.C. § 5705 and its implementing regulations. **NOTE:** *For more information on the PLM QM program, see paragraph 7.*

(15) Assessing the PLM QM program for continuous improvement and effective corrective and preventative actions at defined intervals at a minimum annually.

(16) Selecting and monitoring reference laboratories for quality of service.

(17) When the VA medical facility CLIA Laboratory Director is not stationed at the address on the CLIA certificate, visiting the VA medical facility laboratory in person with the minimum frequencies listed below and documenting these visits, including evidence of performing activities that are part of the VA medical facility CLIA Laboratory Director's responsibilities. **NOTE:** *In person-visits may be delegated for waived and PPM only sites. It is permissible to be visited more frequently than the minimal requirement.*

(a) Non-Waived VA Medical Facility Laboratories. Three times per calendar year with a minimal interval of 3 months between visits.

(b) Non-Waived Health Care Center or Community Based Outpatient Clinics. Two times per calendar year with a minimal interval of 4 months between visits.

(c) Waived Locations. Once per calendar year.

(18) Overseeing the VA medical facility Laboratory Biosafety Officer in determining the biosafety level (BSL) of the VA medical facility laboratory and ensuring all biosecurity and biosafety requirements are met.

(19) Determining the education level, time commitment and experience necessary for the VA medical facility Laboratory Biosafety Officer and ensuring that the VA medical facility Laboratory Biosafety Officer is trained on topics pertaining to biosafety.

(20) Ensuring that VA medical facility PLM providing anatomic pathology services participates in the non-gynecologic (GYN) cytopathology program designated by the Executive Director, PLM, a CMS-approved GYN cytopathology proficiency program and other PT programs designated as mandatory by the Executive Director, PLM.

(21) Certifying the competency of cytotechnologists to report negative GYN cytopathology specimens by written delegation. See paragraph 13.d.

(22) Maintaining documentation of investigations and corrective actions taken for satisfactory PT when the score is less than 100%. See paragraph 6 for more information on PT.

(23) Forwarding documentation of investigations and corrective actions for unsatisfactory PT results to PLM NEO within 25 business days of receipt of the PT evaluation report and maintaining a record within the VA medical facility laboratory.

(24) Ensuring the VA medical facility fulfills all requirements described in paragraph 3 to perform laboratory testing.

(25) Creating and implementing procedures to verify that patient results are accurately transmitted from the point of data entry to patient reports and performing appropriate test result management quality checks. For more information on test result management, see paragraph 8.c.

(26) Defining limits for display system flags for electronic data transmissions and approving auto-verification for significant test results workflow. For more information on electronic data transmission, see paragraph 8.h.

(27) When the VA medical facility laboratory chooses to purchase PT from a vendor other than the vendors under VA contract, authorizing the PT program to release copies of all PT evaluation reports to PLM NEO.

(28) Ensuring the VA medical facility laboratory has procedures in place that addresses patient request that specimens be returned to them after a surgical procedure. For more information on patient specimen requests, see paragraph 13.b.

(29) Completing a JPC requisition form when using JPC pathology consultation. For more information on JPC reference laboratory services, see paragraph 17.

(30) Ensuring all VA laboratory-developed tests are validated using requirements found in 42 C.F.R. § 493.1253(b)(2) and ensuring this validation is documented and readily available for review by the National PLM Quality and Compliance Agent during audit.

o. **VA Medical Facility Administrative Laboratory Chief.** *NOTE: In situations when a qualified pathology physician cannot be successfully recruited to serve as VA medical facility Chief, PLM, a non-pathology physician VA medical facility Administrative Laboratory Chief must be appointed to perform the VA medical facility CLIA Laboratory Director functions and to provide direction and oversight whenever a technical consultant is retained (e.g., consulting pathologist). In addition, a contracted consulting pathology physician must be retained to serve as a pathology technical consultant or technical supervisor and advise the VA medical facility Administrative Laboratory Chief in pathology related issues. Laboratory testing decisions must be made by a VA medical facility Chief, PLM. The VA medical facility Administrative Laboratory Chief is responsible for:*

(1) Serving as the VA medical facility CLIA Laboratory Director when the VA medical facility does not have a VA medical facility CLIA Laboratory Director.

(2) Meeting the personnel qualifications for the appropriate laboratory complexity as outlined in the laboratory director personnel standards in 42 C.F.R part 493, Subpart M as applied in 38 C.F.R. § 17.3500(k).

p. **VA Medical Facility Transfusion Medical Director.** The VA medical facility Transfusion Medical Director is responsible for:

(1) Providing medical and technical oversight of transfusion and donor services.  
**NOTE:** *The VA medical facility Transfusion Medical Director must be a physician with knowledge and experience in transfusion medicine. For more information on blood transfusion policies, see paragraph 12.*

(2) Reporting transfusion complications in accordance with paragraph 12.c.(2).

(3) Providing guidance to services performing therapeutic phlebotomy and perioperative autologous procedures and ensuring the procedures are performed in a manner consistent with AABB standards.

q. **Chair, Transfusion Utilization Review Committee.** The Chair, Transfusion Utilization Review Committee is responsible for ensuring the Transfusion Utilization Review Committee meets at least quarterly to oversee blood utilization reviews and reporting results from these reviews to the VA medical facility CoS. **NOTE:** *For additional information on this committee and blood utilization reviews, see paragraph 12.b.*

r. **VA Medical Facility Pathology Physician.** **NOTE:** *All VA medical facility pathology physicians must be licensed physicians and board certified in anatomic pathology or clinical pathology by the American Board of Pathology.* The VA medical facility pathology physician is responsible for:

(1) Documenting, in writing, all PLM related examinations and reports. See paragraphs 8.e.-g. and 13 for more information.

(2) Participating in pathology-related PT commensurate with their privileges.

(3) For Mohs surgeries that do not have a previous diagnosis documented in the laboratory information system (LIS), attempting to obtain the prior biopsy and reviewing the diagnosis. See paragraph 13.e.

(4) Performing post-mortem examinations as specified in paragraph 16.

(5) Placing the written electron microscopy (EM) report in the patient's EHR within 10 business days after the EM study is requested.

s. **VA Medical Facility Ancillary Testing Coordinator.** The VA medical facility ancillary testing coordinator is responsible for monitoring, overseeing and supporting ancillary testing sites associated with the VA medical facility.

t. **VA Medical Facility Testing Personnel.** *NOTE: VA medical facility testing personnel must meet the qualification requirements of 42 C.F.R. § 493.1363 to perform the functions specified in 42 C.F.R. § 493.1365 for the volume and complexity of laboratory testing performed.* VA medical facility testing personnel are responsible for performing both routine and highly specialized tests for the purposes of diagnosing or aiding in the treatment of disease, troubleshooting (i.e., preventing and solving problems with results, specimens or instruments) and communicating test results to the VA medical facility pathology physician or treating VA health care provider.

u. **VA Medical Facility Designated Laboratory Safety Officer.** The VA medical facility designated laboratory Safety Officer is responsible for monitoring all regulatory elements within the laboratory safety program unless a VA medical facility has a designated, separate VA medical facility Laboratory Biosafety Officer who fulfills all elements described in paragraph 2.v. below. For more information on the VA medical facility designated laboratory Safety Officer, see paragraph 10.

v. **VA Medical Facility Designated Laboratory Biosafety Officer.** The VA medical facility designated Laboratory Biosafety Officer is responsible for, under the oversight of the VA medical facility CLIA Laboratory Director, determining the BSL of the VA medical facility laboratory and ensuring all biosecurity and biosafety requirements are met. See paragraph 10.

### 3. VA LABORATORY TESTING

a. All laboratory testing within VA medical facilities used for the diagnosis, treatment and prevention of disease in patients must comply with the requirements outlined in this directive, 38 C.F.R § 17.3500 and 42 C.F.R. part 493.

b. All laboratory testing within VA must have a submitted electronic laboratory order authorized by a licensed independent provider with the exception of downtime non-electronic orders. Orders placed by non-licensed independent providers authorized per VA medical facility policy must still be entered electronically.

c. These standards must be met for all laboratory services offered within a VA medical facility, outreach functions and ancillary testing sites, regardless of the physical relationship to the VA medical facility's PLM or the administrative service assigned to direct the personnel, research or technical aspects of the testing site.

d. Contracts for laboratory services performed on-site at VA medical facility laboratories, outreach functions and ancillary testing sites must require that these standards be met.

e. All VA medical facilities are regulated, accredited or have compliance verified by a VA-approved laboratory accreditation program with CMS-deemed status. Each VA

medical facility must meet the corresponding laboratory testing requirements of those organizations.

f. If performing transfusion activity the laboratory must also be accredited by AABB and registered or licensed by FDA.

g. VA medical facility laboratories, including community-based outpatient clinic (CBOC) and off-station clinic sites performing waived and PPM testing, must register with PLM NEO and must be assigned a CLIA number as outlined in the interagency agreement between CMS and VA.

h. Laboratory testing, regardless of location, must undergo an on-site inspection by a VA-approved external accrediting agency once every 2 years. Any exceptions must be approved by the PLM National Enforcement Office.

i. When the requirements of the accrediting agency and VA requirements differ, the more stringent requirements supersede.

j. The main VA medical facility laboratory in each VA medical facility must be directed by the VA medical facility Chief, PLM who must be a U.S. Federal employee, a licensed physician and board certified in anatomic pathology, clinical pathology or both by the American Board of Pathology. The VA medical facility laboratory and anatomic pathology services are under the direction of the VA medical facility Chief, PLM. The VA medical Chief, PLM must have the appropriate training and background to meet the requirements of 42 C.F.R. § 493.1443 as applied in C.F.R. § 17.3500(k). Any exceptions must be approved by the Executive Director, PLM.

k. Specialty laboratories that fall outside the accreditation umbrella of the VA medical facility main laboratory may have a non-pathology physician or an individual with a doctoral degree in chemical, physical or biological science appointed to serve as the VA medical facility CLIA Laboratory Director. The VA medical facility Chief, PLM must serve as a consultant for specialty laboratories and ensure that testing is carried out in compliance with 38 C.F.R. § 17.3500 and 42 C.F.R. part 493 and VHA policies. Testing must be overseen under the ancillary testing program. The VA medical facility CLIA Laboratory Director must:

(1) Be qualified by documented training, expertise and experience in analytical testing and biological, chemical or clinical science specifically related to the VA medical facility laboratory's special testing functions.

(2) Meet the laboratory director qualifications required by 42 C.F.R. part 493, Subpart M and must be able to discharge the responsibilities cited in 42 C.F.R. part 493, Subpart M as applied in C.F.R. § 17.3500(k) and this directive.

(3) Have their appointment approved by the VA medical facility Chief, PLM and the National PLM Quality and Compliance Officer.

l. The scope of testing and services provided by anatomic and clinical pathology services must be appropriate for the nature of the patient care services at the VA medical facility. The VA medical facility PLM must either perform those tests and services required to provide quality care to patients or arrange for these services to be performed by a laboratory that is currently accredited by a CMS-approved accreditation organization, has CMS CLIA exempt status or is approved by the National PLM Program Office.

m. Research laboratories within VHA may only report clinical laboratory results if they meet the requirements of CLIA, have obtained appropriate CLIA certification and follow all aspects of this directive.

n. Actual or potential patient safety events must be reported in the VHA-mandated reporting systems as outlined in VHA Directive 1050.01, VHA Quality and Patient Safety Programs, dated March 24, 2023.

o. All VA medical facility PLM must provide to their staff a visual resource on where and how to access PLM-related information. This visual resource must be physically posted in a location where staff can access this information, at any time. The resource shall be provided by the National PLM Program Office. This visual resource must have, at minimum, the following:

(1) The National PLM Program Office contact information ([VHAPLMSPProgramOffice@va.gov](mailto:VHAPLMSPProgramOffice@va.gov)) and intranet website: <https://vaww.lab.med.va.gov/index.asp>. **NOTE:** This is an internal VA website that is not available to the public.

(2) Information on how patients, visitors and laboratory staff can anonymously communicate their concerns regarding safety or quality to PLM NEO.

(3) Information on how to locate this directive online.

#### **4. VA CLINICAL LABORATORY IMPROVEMENT AMENDMENTS APPLICATION PROCESS**

a. All VA medical facility testing sites must register with PLM NEO to obtain a CLIA certificate. CBOCs that perform tests categorized as waived or PPM testing procedures must register with PLM NEO and obtain a CLIA certificate. Testing sites meeting VA and Federal regulations and accreditation requirements for patient testing are reviewed by PLM NEO and, if approved, are issued a CLIA number.

b. Each VA medical facility and outpatient clinic laboratory that performs patient testing must be issued a separate CLIA number.

c. Laboratories within a VA medical facility that are located on the same campus and under common direction must file a single application. The National PLM Quality and Compliance Officer must determine whether single or multiple CLIA certificates are required for campuses exceeding one mile in distance.



d. All ancillary testing sites under the accreditation umbrella of the main VA medical facility laboratory must be included under the main VA medical facility laboratory CLIA registration.

**e. Clinical Laboratory Improvement Amendments Application Process.**

(1) A CLIA application must be submitted with a current copy of the listed VA medical facility CLIA Laboratory Director's Curriculum Vitae.

(2) A CLIA Certificate or CLIA Application Letter of Acknowledgement from PLM NEO must be obtained prior to the initiation of testing.

**f. Laboratory Director Qualifications.**

(1) Only a qualified, U.S. Federal employee, licensed physician, board certified in anatomic, clinical pathology or both by the American Board of Pathology may serve as the VA medical facility CLIA Laboratory Director of a VA medical facility laboratory.

(2) The VA medical facility CLIA Laboratory Director must meet the laboratory director requirements for the appropriate complexity of testing as stated in 42 C.F.R. part 493 Subpart M and applied in 38 C.F.R. § 17.3500(k) and be qualified by documented training, expertise and experience in the areas of analytical testing and biological, chemical or clinical science specially related to the testing sites testing functions. When laboratory testing is performed at testing sites (e.g., a CBOC or specialty laboratory) for which the VA medical facility Chief, PLM is not the VA medical facility CLIA Laboratory Director (signer of the CLIA certificate), the VA medical facility Chief, PLM must provide oversight and assistance to ensure that laboratory testing complies with VHA policies.

**g. Clinical Laboratory Improvement Amendments Certificate.**

(1) VA medical facility laboratories must revalidate CLIA certificates with PLM NEO once every 2 years.

(2) VA medical facility laboratories and testing sites issued a CLIA certificate must notify PLM NEO of the following changes within 30 business days:

- (a) VA medical facility laboratory name.
- (b) VA medical facility laboratory location or address.
- (c) VA medical facility CLIA Laboratory Director.
- (d) The addition of a specialty or subspecialty.
- (e) The deletion of a specialty or subspecialty.

(3) VA medical facilities that intend to enact new testing programs or change existing testing programs must submit a Clinical Restructuring Request. See Directive 1043, Restructuring of VHA Clinical Programs, dated September 2, 2016, for more information.

## 5. ACCREDITATION AND COMPLIANCE VERIFICATION REQUIREMENTS

a. Testing sites that perform tests categorized as moderate or high complexity (non-waived) laboratory testing must be accredited or have compliance verified by a VA-approved laboratory accreditation program CMS-deemed status organization. Accreditation or compliance verification inspections for these testing sites must be performed once every 2 years.

b. Primary accreditation and compliance verification and inspection performed once every 2 years for all VA non-waived testing sites must be coordinated under a nationwide contract managed by the Executive Director, PLM.

c. Accreditation and compliance verification inspection teams of VA medical facility laboratories or laboratories performing anatomic pathology, including Mohs surgery, must include a pathology physician inspector to provide pathology clinical review.

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

e. CBOCs or other testing sites performing non-waived testing that are located at a separate address or campus cannot be included under the main VA medical facility laboratory's accreditation or compliance process but must undergo their own accreditation or compliance process.

f. Testing sites that perform only waived testing or PPM testing performed by privileged providers must be inspected as a part of the main VA medical facility laboratory accreditation program or must be accredited or compliance verified and inspected as a part of the main VA medical facility accrediting or compliance verification process. Reaccreditation or compliance verification inspections for these sites must be conducted as required by the respective accrediting or compliance organization.

g. VA medical facility laboratories that perform transfusion services and immunohematology testing must maintain AABB accreditation.

h. **United States Food and Drug Administration Registration.** If a VA medical facility has a blood donor program or provides transfusion services, they must register with the FDA annually.

## 6. PROFICIENCY TESTING

All VA medical facility laboratories and ancillary testing sites that perform laboratory testing on patients must participate in external CMS-approved PT programs for all analytes for which PT is available including waived testing, PPM and non-regulated analytes. All VA medical facility laboratories must maintain successful performance for all test methods and analytes.

a. **Proficiency Testing Requirements.** The VA medical facility laboratory and all ancillary testing locations must perform and report PT from a CMS-approved provider or program approved by the National PLM Quality and Compliance Officer for every instrument and method (including backups) utilized for patient testing and for every testing site where patient testing is performed. The number of PT challenges and PT shipments required for regulated analytes or subspecialties must comply with 42 C.F.R. part 493 Subpart I. Non-regulated analytes must comply with requirements for PT challenges and shipments as described in this directive.

(1) VA medical facility laboratories must order a separate PT kit for each instrument, method and site utilized for patient testing. All PT challenges provided in one PT kit for a specific analyte must be run on the same instrument, method and testing site to allow the tracking of the instrument, method and testing performance throughout the year. The same serial number instrument or manual method must be performed on the same PT kit sequence number for each PT event.

(2) VA medical facility laboratories ordering multiple identical PT kits must not participate in correlation or comparison of PT results prior to the submission cutoff date.

(a) VA medical facility laboratories testing personnel must handle the specimens in each PT kit as unique specimens and run in the same manner as patient specimens.

(b) The same individual cannot perform multiple PT kits of the same PT survey for the same testing event. PT specimens must be rotated and performed with equal frequency by all testing personnel.

(c) VA medical facility laboratories must submit PT survey results to the PT provider from the CLIA site where testing was performed.

(3) Anatomic Pathology must participate in a CMS-approved GYN cytopathology PT program and PT programs for general immunohistochemistry and predictive markers, as appropriate for the types of cases under review. For additional required educational programs refer to paragraph 13.

(4) PT procurement must be coordinated under a national VA contract managed by the Executive Director, PLM.

(5) If the VA medical facility laboratory chooses to purchase PT from a vendor other than the vendors under VA contract, the VA medical facility CLIA Laboratory Director

must authorize the PT program to release copies of all PT evaluation reports to PLM NEO.

(6) For analytes that do not have formal PT available, an alternative PT method must be in place to assess the method accuracy at least twice a year.

**b. Proficiency Testing Evaluation.**

(1) **Evaluation Criteria for Regulated Analytes.** CMS-determined analyte-specific evaluation criteria and target values used to grade each result for regulated analytes can be found in 42 C.F.R. part 493 Subpart I. VA medical facility laboratories must use this grading criteria for regulated analytes.

(2) **Evaluation Criteria for Non-Regulated Analytes Formally Evaluated by the Proficiency Testing Provider.** CMS-approved PT providers 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 VA medical facility laboratory's PT survey report and must be used by the VA medical facility laboratory.

(3) **Evaluation Criteria for Analytes Not Formally Evaluated by the Proficiency Testing provider.** Quantitative PT challenges must be graded as plus or minus three standard deviations (+/- 3SD) or plus or minus three standard deviation index (+/- 3SDI) of the appropriate peer group mean. Tests for enzymes not formally evaluated must be scored as +/- 20% of the peer group means. Qualitative PT challenges are graded against the intended response.

**c. Proficiency Testing Scoring.**

(1) For PT events with multiple PT kits ordered, each PT kit is scored individually. To determine the score for the analyte testing PT event, the percent of acceptable analyte responses must be calculated as follows: (number samples or analyte correct times 100) divided by total number PT challenges or analyte.

(2) If the formal or in-house PT is scored less than 100%, the VA medical facility laboratory must immediately investigate to determine the cause and take corrective action to maintain reliable patient testing performance.

(3) VA medical facility laboratory investigations must minimally include a review of:

- (a) Clerical errors.
- (b) Technical or methodological issues.
- (c) Problems with PT material.
- (d) PT specimen handling.

- (e) Quality control, maintenance and service records.
- (f) Policies and procedures.
- (g) Performance on previous PT surveys.

(4) The VA medical facility laboratory's corrective action plan and supporting documentation must address:

- (a) The details of the investigation including root cause.
- (b) The retesting of the PT challenge(s), if possible.
- (c) An evaluation of patient results since the last successful PT event and action taken as needed.
- (d) Corrective action taken to prevent or minimize future recurrences.
- (e) Staff education and training with documentation of date, material covered and persons attending, if applicable.

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

- (a) A score of 100% in blood group and type (ABO/Rh) unexpected antibody detection or compatibility testing.
- (b) A score of 80% or greater for an analyte in a PT event which is composed of five PT challenges.
- (c) A score of greater than 50% for an analyte in a PT event which is composed of fewer than five PT challenges.
- (d) The VA medical facility CLIA Laboratory Director must maintain documentation of investigation and corrective action taken for satisfactory PT when the score is less than 100%.

(6) **Unsatisfactory Proficiency Testing Event.** Failure to attain a minimum satisfactory score on a single PT event is described as:

- (a) A score of less than 100% in ABO/Rh, unexpected antibody detection or compatibility testing.
- (b) A score of less than 80% for an analyte in a PT event which is composed of five PT challenges.
- (c) A score of 50% or less for an analyte in a PT event which is composed of fewer than five PT challenges.

(d) Failure to participate or return PT results to the PT provider within the timeframe specified by the PT program is unsatisfactory performance and results in a score of zero for the PT event. The VA medical facility laboratory must perform an alternate accuracy assessment for affected analytes on that PT event. Consideration must be given to those VA medical facility laboratories failing to participate in a PT event if:

1. Patient testing was suspended or not implemented during the timeframe allotted for testing and reporting PT results.

2. An issue with the PT material prevented reporting of results.

3. The VA medical facility laboratory participated in the previous two PT events.

(e) The VA medical facility CLIA Laboratory Director must forward documentation of investigation and corrective action for unsatisfactory PT results to PLM NEO within 25 business days of the receipt of the PT evaluation report and maintained a record within the VA medical facility laboratory.

**d. Proficiency Testing Failure or Unsuccessful Participation.** PT failure or unsuccessful participation is described as:

(1) A score of less than 100% on two out of three consecutive PT events in ABO/Rh, antibody identification and compatibility testing.

(2) A score of less than 80% on two out of three consecutive PT events for an analyte event which is composed of five PT challenges.

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

(4) An overall score of less than 80% on two out of three consecutive PT events for a specialty or subspecialty.

(5) A score of zero on two out of three consecutive PT events for failure to submit results to the PT provider within the specified timeframe. Consideration will be taken if patient testing was suspended during the PT event.

**e. Proficiency Testing Failure Reinstatement Protocol.** In the event of a PT failure for an analyte, the VA medical facility laboratory must:

(1) Cease laboratory testing for the specific analyte(s) on the suspect instrument or method. It is only necessary to cease laboratory testing on the instrument or method which had the PT failure.

(2) Immediately investigate the circumstances of the events that led to the PT failure. The decision to resume laboratory testing is made after the review of the information and approval by PLM NEO.

(3) At the VA medical facility's expense, perform two remedial PT events from a CMS-approved PT provider and ensure that the results and the supporting data are sent to PLM NEO.

(a) If no CMS-approved PT provider exists for the failed analyte, the affected VA medical facility laboratory and PLM NEO must determine how testing must be reinstated at the VA medical facility (e.g., a split sample sent to the VA medical facility laboratory's usual reference laboratory). The results from the remedial PT or alternative PT must be sent to PLM NEO for review.

(b) When the cause of the PT failure does not affect patient care, the performance of a remedial PT event must be at the discretion of PLM NEO.

(4) PLM NEO must review the VA medical facility laboratory's investigation, corrective action plan, the results of the remedial testing and supporting data. Laboratory testing may resume when there is approval of the remedial PT and the VA medical facility laboratory's corrective action plan by PLM NEO.

(5) Resumption of laboratory testing may be authorized once the VA medical facility laboratory verifies the following conditions are met:

(a) There is no immediate jeopardy to patient health and safety. **NOTE:** *Immediate jeopardy is a situation in which immediate corrective action is necessary because the VA medical facility laboratory's noncompliance with one or more requirements has already caused, is causing or is likely to cause, at any time, serious injury or harm or death to individuals served by the VA medical facility laboratory or to the health or safety of the public.*

(b) The VA medical facility laboratory provides PLM NEO with satisfactory evidence that steps were taken to correct the problem identified by the unsuccessful PT performance.

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

(6) The VA medical facility laboratory, as part of its QM program, must periodically reassess the implemented corrective action to ensure continued compliance to prevent the problem from reoccurring.

## **7. PATHOLOGY AND LABORATORY MEDICINE QUALITY MANAGEMENT PROGRAM**

a. VA medical facilities, their outreach functions and ancillary testing sites that perform laboratory testing must have a defined PLM QM program. **NOTE:** *VHA QA and QM activities generate confidential documents that may be protected as defined in 38 U.S.C. § 5705 and its implementing regulations.*

b. The VA medical facility must provide an ongoing, comprehensive PLM QM program under the direction of the VA medical facility Chief, PLM and VA medical facility CLIA Laboratory Director, which:

(1) Evaluates the effectiveness of the VA medical facility PLM program and procedures throughout all pre-analytical, analytical and post-analytical phases of the laboratory testing process.

(2) Ensuring the availability of test results and reports that are accurate, reliable and of high quality.

(3) Documents and evaluates all PLM QM program activities.

c. The PLM QM program must be defined in a written PLM QM plan that provides a comprehensive, systematic approach that encompasses all sections of the VA medical facility laboratory such as clinical pathology, anatomic pathology and ancillary testing. There must be an on-going, planned, systematic and objective process for the monitoring and evaluation of PLM QM plan effectiveness and the appropriateness of patient care provided by the VA medical facility PLM.

d. **Quality System Essentials for Laboratory Services and Ancillary Testing Sites.** VA medical facility laboratories and ancillary testing sites must use the Quality System Essentials (QSE) model defined by the Clinical Laboratory Standards Institute or QSE format defined by the laboratory accreditor to structure, establish and define the VA medical facility laboratory PLM QM plan. The PLM QM plan must be assessed and approved by the VA medical facility CLIA Laboratory Director once a year.

e. **Correlation Requirements.**

(1) FDA-approved analytical systems must have a system in place to ensure that all test methods are verified prior to implementation. The verification protocol is at the discretion of the VA medical facility CLIA Laboratory Director but at a minimum must meet the manufacturer's recommendations, regulatory requirements and correlate the new test method/instrument to current test method/instrument. The verified protocol must be approved by the VA medical facility CLIA Laboratory Director.

(2) Non-waived to waived correlations must be performed on rotating subsets of the waived instruments and methods twice a year. The VA medical facility CLIA Laboratory Director must determine the size of the subsets.

(3) For testing sites located on a different campus or address but within the same health care system, correlations must be performed between the main VA medical facility laboratory and the remote testing site to define an initial relationship between all test methods and instruments (waived and non-waived) prior to the implementation of new tests or methodologies.



f. **Sentinel Event Reporting.** Adverse events, sentinel events or deaths related to laboratory testing must be reported to the National PLM Quality and Compliance Agent, the National PLM Quality and Compliance Officer, the Executive Director, PLM and FDA, if applicable.

## 8. TEST RESULT REPORTING AND INFORMATION TECHNOLOGY

### a. **System Verification and Validation.**

(1) All software (including middleware), hardware or configuration changes must be verified and approved by the VA medical facility CLIA Laboratory Director prior to implementation. If specific verification protocols are required by VHA, they must be utilized.

(2) All software patches mandated by VHA must be implemented and individually validated at the VA medical facility or VISN level.

(3) VA medical facilities must use VA-approved EHR software for all blood bank or transfusion practices. Work must be documented in the EHR as the activity is performed. Local modifications to the VA blood bank systems are prohibited.

(4) Calculations performed by middleware or LIS must be validated. Downtime contingency plan and procedures must be in place when middleware calculations are not available or bypassed.

(5) Auto-verification processes must be validated prior to implementation, including vendor-provided rule sets implemented by the VA medical facility laboratory.

### b. **Standardized Coding Requirements.**

(1) LIS test file structure must include standardized current procedural terminology (CPT) codes, Logical Observation Identifier Names and Codes (LOINC) and National laboratory tests (NLT) workload codes. **NOTE:** *LOINC is an international standard for identifying medical and laboratory observations that can be stored in an EHR. NLT are VHA-specific codes used for purposes of conveying CPT, LOINC, test order codes, test result codes, workload and relative value units dependent upon location of its use within LIS.*

(2) Anatomic Pathology reporting must contain CPT codes and Systemized Nomenclature of Medicine (SNOMED) codes, including those required by the Executive Director, PLM.

### c. **Test Result Management.**

(1) There must be procedures to verify patient results are accurately transmitted from the point of data entry (interfaced instruments and manual input) to patient reports.

(2) Comparison between the procedure, instrument, middleware and EHR must be performed at least once every 2 years to verify test results, reference ranges, abnormal result flags and results outside of the reportable range (“<” and “>”) display correctly for each test and specimen type.

(3) Test systems compatible with LIS and meet VA information security requirements, must be interfaced to LIS.

(4) There must be a quality control process to ensure test results manually entered into LIS are accurate and complete.

(5) Laboratory tests ordered by a VA health care provider or contract health care provider for use in providing patient care and tested by a VA medical facility laboratory, VA-contracted laboratory (e.g., reference laboratories) or agent of the VA laboratory must be entered into LIS.

(a) For reports captured outside of LIS, the test must be accessioned into LIS and the location of the imaged document entered in the comment section of the results following EHR procedures. The VA medical facility CLIA Laboratory Director must approve the types of test reports that utilize programs outside of LIS.

(b) There must be a quality control process in place to ensure scanned reports include accurate patient identification and are complete and legible.

(c) For anatomic pathology reports received from a reference laboratory, at a minimum, the diagnosis and SNOMED must be entered in LIS pathology package with the full report scanned into EHR or the full report transcribed into LIS.

(d) Mohs surgery cases must be accessioned and reported in the LIS pathology package. If the full report is not entered into the LIS pathology package, at a minimum the diagnosis and SNOMED code must be entered and linked to the Mohs surgery case number and location of full report in EHR.

(6) Privileged provider performed test results must be entered in the patient’s EHR.

(a) Qualitative results of waived or PPM testing performed by privileged providers as part of the patient exam must be entered into either LIS as a result or the EHR utilizing a VA medical facility CLIA Laboratory Director approved title note or template to ensure results are searchable.

(b) All other qualitative or quantitative results must be entered into LIS.

(7) Results of tests ordered by a community care provider and used by a VA provider to treat or monitor a VA patient, as in shared or co-managed patients, must be documented in the patient’s EHR.

(8) Patient self-test results must not be entered into LIS.

d. **Test Reports.** All test reports must be compliant with CLIA regulations. Additional requirements for specialties and subspecialties are listed below.

(1) **Anatomic Pathology.**

(a) Identity of the patient's health care provider.

(b) Identity of the submitting health care provider.

(c) Pertinent clinical or sample information and other instructions contained on the requisition.

(d) Unique accession number of the specimen.

(e) Name and authentication of the responsible VA medical facility pathology physician.

(f) Dates when the specimen was obtained, specimen was accessioned and diagnostic result(s) verified by the VA medical facility pathology physician.

(2) **Cytopathology.** In addition to report requirements listed in anatomic pathology, if cytology slides are screened prior to review by the responsible VA medical facility pathology physician, the final cytopathology report must include the name of the screener.

(3) **Electron Microscopy Report.**

(a) A written or electronic report must be issued promptly on each patient specimen using LIS EHR. Any verbal communication of the result must be documented in the final written report. The VA medical facility pathology physician must place the written report in the patient's EHR within 10 business days after the EM study is requested.

(b) The report must include:

1. Dates when the specimen was accessioned and diagnostic result(s) verified by the VA medical facility pathology physician.

2. A description of the light and EM findings.

3. A specific diagnosis.

4. Where appropriate, the pertinent literature reference.

(c) The report must be signed by the VA medical facility pathology physician making the diagnosis. Selected digital images of excellent quality and key diagnostic value must be uploaded to the patient's EHR.

(4) **Post-Mortem Examinations.** Refer to paragraph 16 of this directive.

(5) **Copies.** Upon appropriate request, only electronic or paper copies of verified reports may be circulated within VA medical facilities.

**e. Laboratory Report Correction.**

(1) Correcting, altering, retracting, deleting or otherwise changing laboratory reports in LIS must conform to VHA policy and local Health Information Management (HIM) procedures for health record alteration and modification.

(2) If an error is found on a released-patient laboratory result, the laboratory must communicate immediately with the ordering health care provider and document the communication in LIS including name of person notified and date and time of the notification. The VA medical facility CLIA Laboratory Director must ensure that the report is corrected in LIS. Both original and corrected results must be retained according to PLM record retention guidelines, which are available at <https://dvagov.sharepoint.com/sites/VHADiagnosticservices/PLMS/edcen/SitePages/Laboratory-Accreditation.aspx>. **NOTE:** *This is an internal VA website that is not available to the public.*

(3) Only authorized personnel must be assigned the security keys by the VA medical facility CLIA Laboratory Director to remove changed or deleted result comments generated by LIS. At least once a year, review of security key holders must be conducted to ensure continued appropriateness of security key distribution.

(4) Requests for report amendment (any modification, correction, addition, retraction or deletion) initiated by a Veteran, patient or their agent must be routed to the VA medical facility Privacy Officer for processing.

(5) There must be an auditing process for modified, corrected and retracted reports, as part of the laboratory's PLM QM Program.

**f. Anatomic Pathology Report Correction.**

(1) All report corrections for anatomic pathology must adhere to the OPPE Guide 3, available at: <https://dvagov.sharepoint.com/sites/VHADiagnosticservices/PLMS/edcen/SitePages/Laboratory-Accreditation.aspx>. **NOTE:** *This is an internal VA website that is not available to the public.*

(2) Modified reports must describe the change from the original report.

(3) Both original and corrected results must be retained according to the record retention requirements.

(4) The date and time of the modification must be included as part of the report.

(5) A modified report must only be made by the VA medical facility pathology physician that originally signed the case. A modification by another VA medical facility

pathology physician must only be made with the understanding that the VA medical facility pathology physician making the modification is taking full responsibility for the report. In this circumstance, the modified report must clearly indicate the change in reporting VA medical facility pathology physician.

(6) Tracking of the modified reports must be monitored as part of the Anatomic Pathology QM program. For more information on the Anatomic Pathology QM program, see paragraph 13.g.

(7) If the supplemental or modified report represents a clinically significant change that may alter patient management, the VA medical facility pathology physician must communicate the change immediately to the ordering provider (or responsible surrogate) and document the communication in LIS including name of person notified and date and time of the notification.

**g. Laboratory Report Retraction.**

(1) Only in rare circumstances may a laboratory report be administratively deleted or retracted by authorized staff from active display in the EHR. An example would be a report entered under the wrong patient or wrong accession number. The report retraction process must follow VHA Directive 1907.01(1), VHA Health Information Management and Health Records, dated April 5, 2021, and local procedures for record retraction (e.g., HIMS).

(2) Only authorized staff must have the security keys to delete or retract reports that have already been verified. Review of security key holders must be conducted minimally once a year.

(3) To prevent action by other VA health care providers based on wrong patient information the report must be modified or corrected immediately upon discovery.

(4) The correction must include the error identified and directions to the viewer to disregard report contents.

(5) If after review, the error is determined to be clinically significant and the timing is such that clinical decisions may have been made based on the erroneous report, the ordering VA health care provider must be notified and the communication documented in LIS including name of person notified and date and time of the notification.

(6) The report must be expeditiously retracted. While retracted documents are not considered part of the complete health record and are not visible, they must be retained and may be recovered if required for medicolegal or other purposes.

(7) If clinically significant delay in care, inappropriate patient management or other harm occurred, the VA medical facility QM office must be notified.

(8) VA medical facilities must have an auditing process of retracted reports.

#### **h. Electronic Data Transmission/Instrument Interface to the Laboratory Information System.**

(1) The VA medical facility laboratory must have clearly written procedures of system checks on entered data to:

(a) Display system flags for high, low and critical values using predefined limits established by the VA medical facility CLIA Laboratory Director.

(b) Prohibit the entry of results outside of predefined limits.

(c) Display CLIA Laboratory Director-defined delta checks against previous patient tests result prior to verification. **NOTE:** *A delta check is a quality control tool that compares laboratory test results with results obtained on previous samples from the same patient.*

(d) Configure auto-verification rules to hold significant test results for review and manual release to LIS. The auto-verification workflow must be approved by the VA medical facility CLIA Laboratory Director prior to implementation.

(e) Identify significant abnormalities entered into LIS by a visual flag observed next to the test values.

### **9. INFECTION CONTROL ACTIVITIES**

a. VA medical facility laboratories are required to facilitate infection control activities and investigations.

#### **b. Infection Prevention and Control Committee.**

(1) Each main VA medical facility laboratory must have at least one permanent representative to serve on the VA medical facility Infection Prevention and Control Committee. For more information see VHA Directive 1131, Management of Infectious Diseases and Infection Prevention and Control Programs, dated November 27, 2023.

(2) Each VA medical facility laboratory must work with the Infection Prevention and Control Committee or the VA medical facility Infection Control Officer to define the type of and required frequency of infection control reports to be presented. **NOTE:** *Infection control reports are surveillance activities to identify and monitor the rate of nosocomial infections. Infection control reports are considered medical quality control records and are covered under 38 U.S.C. § 5705 and its implementing regulations.* Reports to infection control at a minimum must include:

(a) Cumulative antimicrobial susceptibility data (antibiogram) at least once a year.

(b) Microorganisms required to be reported to local or State health departments in accordance with local information sharing agreements and consistent with VHA Directive 1131. Frequency is dependent on local guidelines.

(c) Organisms that necessitate special isolation procedures (e.g., multiple antibiotic resistant organisms), unless there is an existing automatic reporting system in place for alerting infection control. Minimum frequency is determined in consultation with the Multi-Drug Resistant Organism Prevention Coordinator and the Infectious Disease, Infection Prevention and Control Staff and current VA guidelines.

(d) Monitors for skin contaminants in blood cultures at least once every 3 months.

(e) Results of cultures or laboratory testing (e.g., Legionella) required for the infection control group to comply with accreditation and VA standards. Minimum frequency is dependent on local and national requirements.

(f) Other quality management reports, as appropriate.

c. **Food-Borne Illnesses.** If food-borne illness outbreak is suspected among VA employees or patients, the VA medical facility laboratory must consult with the appropriate local, State or Federal public health service laboratory for epidemiological and laboratory assistance.

## 10. LABORATORY SAFETY, BIOSECURITY AND BIOSAFETY

### a. **Laboratory Safety.**

(1) All VA medical facility laboratories must have a VA medical facility designated laboratory Safety Officer.

(2) All VA medical facility laboratories must have a VA medical facility designated Laboratory Biosafety Officer.

(a) Under the oversight of the VA medical facility CLIA Laboratory Director the Laboratory Biosafety Officer must determine the biosafety level (BSL) of the VA medical facility laboratory and must ensure all biosecurity and biosafety requirements are met.

(b) The VA medical facility CLIA Laboratory Director must determine the education level, time commitment and experience necessary to perform the job and ensure that the Laboratory Biosafety Officer is trained on topics pertaining to biosafety.

(3) The laboratory Safety Officer may also serve as the Laboratory Biosafety Officer. If the laboratory Safety Officer is separate from the Laboratory Biosafety Officer, the laboratory Safety Officer's responsibilities cover all regulatory elements within the laboratory safety program not already covered under the umbrella of the Laboratory Biosafety Officer (e.g., electrical and fire hazards, chemical hygiene, workplace safety conditions).

### b. **Laboratory Biosecurity and Biosafety.**

(1) All VA medical facility laboratories that perform laboratory testing on patients must be compliant with the following:

(a) VA medical facility laboratories must meet the applicable clinical laboratory requirements for handling, reporting and destroying select agents as defined in 42 C.F.R. part 73 and the CDC's Federal Select Agent Program website found at: <https://www.selectagents.gov/>. **NOTE:** *Select agents are biological agents and toxins that could pose a severe threat to public or plant health or to animal or plant products.*

(b) Biosafety measures, including utilization of BSL facilities, must be handled in accordance with CDC recommendations as described in the most current edition of the Biosafety in Microbiological and Biomedical Laboratories manual, available at <https://www.cdc.gov/labs/BMBL.html>.

## (2) Biosafety Level Determination and Activities.

(a) A risk assessment must be performed for all VA medical facility laboratories or sections of the pathology and medicine service where clinical testing takes place to designate a BSL to the VA medical facility laboratory.

(b) VA medical facility laboratories routinely culturing patient specimens for microbiological organisms must meet as a minimum, the BSL-2 facility and personnel training requirements.

(c) In the absence of a BSL-3 facility, Mycobacterium tuberculosis (*M. tuberculosis*) cultures may be performed in a BSL-2 laboratory which must have specific BSL-3 features (engineering and barrier) and BSL-3 practices that allow for safe performance of cultures as determined by a risk assessment performed by a multidisciplinary group led by the designated VA medical facility Laboratory Biosafety Officer.

(d) Acid Fast Stains (AFB) smears prepared in a BSL-2 laboratory must be limited to direct AFB smears only. Concentrated AFB smears must be prepared only in a properly certified BSL-3 laboratory or a BSL-2 laboratory with specific BSL-3 features and practices that allow for safe performance as determined by the risk assessment noted above.

(e) BSL-3 and BSL-2 laboratories with enhancements for Mycobacterial manipulation as defined above must be assessed annually by a multidisciplinary group (e.g., industrial hygienist, engineering, infection control, microbiology) led by the VA medical facility designated Laboratory Biosafety Officer or a contracted certification company. An sample risk assessment can be found on the PLM intranet site: <https://dvagov.sharepoint.com/sites/VHADiagnosticservices/PLMS/edcen/SitePages/Laboratory-Accreditation.aspx>. **NOTE:** *This is an internal VA website that is not available to the public.*

(f) VA medical facilities that isolate and identify cultures of *M. tuberculosis* from six or fewer patients per year (low exposure) must ensure that VA medical facility laboratory employees working in the mycobacterial testing laboratory are tested for exposure at least once every 12 months.



(g) VA medical facilities isolate and identify cultures of *M. tuberculosis* from more than six patients per year (high exposure) must ensure that VA medical facility laboratory employees working in the mycobacterial testing laboratory are tested for exposure at least once every 6 months.

## 11. ANCILLARY TESTING

a. Ancillary testing includes waived, PPM and non-waived testing performed outside of the physical limits of the main VA medical facility PLM and performed by VA medical facility laboratory or non-laboratory personnel.

b. A VA medical facility ancillary testing coordinator must be designated in writing by the VA medical facility CLIA Laboratory Director to monitor and oversee the ancillary testing sites. The VA medical facility ancillary testing coordinator or full-time equivalent must be commensurate to supporting the ancillary testing program.

c. Ancillary testing instruments must be cleaned and disinfected according to manufacturer's instructions and VHA reusable medical equipment protocols.

### d. Patient Self-testing.

(1) Patients may perform self-testing within a VA medical facility when self-testing is required as part of a patient education program or when the patient is in a domiciliary or similar situation and adjusting their own medication.

(2) PLM does not provide regulatory oversight of patient self-testing programs.

(3) Patient self-testing is managed under the VA medical facility patient self-testing program. The VA medical facility Chief, PLM may provide consultation or collaboration when requested, but the VA medical facility patient self-testing program is not managed by the laboratory's ancillary testing program. Refer to VHA Directive 1138, Patient Self-Testing for Monitoring of Prothrombin Time International Normalized Ratio in Patients on Warfarin Anticoagulation Therapy, dated January 27, 2023, for more information on patient self-testing.

(4) The decision as to whether VA health care providers may treat a patient based on the patient's self-testing results must be made by the VA medical facility leadership.

(5) The VA medical facility Chief, PLM 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 is appropriate for the intended use.

(b) Device selection meets VA and regulatory requirements.

(c) Development of protocols for test method validation. The VA medical facility Chief, PLM serves as a subject matter expert for validation as needed.

(d) Development of test protocols. The VA medical facility Chief, PLM serves as a consultant as needed.

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

## 12. TRANSFUSION SERVICES AND IMMUNOHEMATOLOGY

### a. General Policies.

(1) VA medical facilities that provide transfusion services must be accredited by the AABB.

(2) VA medical facilities that provide transfusion services must register with FDA. Any blood donor activity must be approved by PLM NEO prior to implementation.

(3) VA medical facilities must use VA-approved EHR software for documenting all blood bank or transfusion practices. Local modifications to the VA blood bank software are strictly prohibited.

(4) VA medical facilities that contract pre-transfusion testing and perform only storage and distribution of products must meet the applicable requirements in this directive, all VHA policies and accreditation requirements.

(5) Contracted services related to transfusion must meet supplier qualification requirements specified by AABB.

(6) Transfusion-associated fatalities and biological product deviations must be reported directly to the FDA and a copy forwarded to PLM NEO.

### b. VA Medical Facility Blood Transfusion Utilization Review Committee.

(1) **Blood Utilization Review.** Blood utilization review is the review of the following metrics by a clinical review committee to minimize the inappropriate use of blood components and promote transfusion of the right component at the right time to the right patient:

(a) Ordering practices.

(b) Patient identification.

(c) Sample collection and labeling.

(d) Infectious and noninfectious adverse events.

(e) Near-miss events.

(f) Usage and wastage data.

(g) Appropriateness of use, including group O and group O Rh(D)-negative red blood cells and AB plasma use.

(h) Blood administration policies.

(i) Ability of services to meet patient needs.

(j) Compliance with clinical-review recommendations.

(k) Clinically relevant laboratory results.

(2) VA medical facilities that transfuse blood or blood products must have a VA medical facility Blood Transfusion Utilization Review Committee. The VA medical facility Blood Transfusion Utilization Review Committee Chair must be a provider with knowledge and experience in transfusion medicine. The VA medical facility Blood Transfusion Utilization Review Committee must be composed of multidisciplinary members knowledgeable and experienced in one or more aspects of transfusion therapy and blood banking. The VA medical facility Blood Transfusion Utilization Review Committee must review transfusion-related activities and meet requirements of AABB standards. The VA medical facility Blood Transfusion Utilization Review Committee must meet at least once every 3 months.

(3) VA medical facility Transfusion Services must develop and maintain a QM plan utilizing the AABB QSE framework. The QM plan must address quality and regulatory aspects of transfusion activities.

**c. Technical Policies.**

**(1) Transfusion Services.**

(a) VA medical facilities that provide transfusion or blood donor services must only use blood components from volunteer non-remunerated blood donors.

(b) Technical activities in transfusion services must follow current AABB Standards for Blood Bank and Transfusion Services.

**(2) Transfusion Complications.**

(a) Suspected transfusion reactions occurring in VA medical facilities for which VA has investigational responsibility, including home transfusions or transfusions in extended care centers, must be promptly investigated.

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

(c) Events considered sentinel events by hospital accreditation organization must be reported to the Executive Director, PLM and the National PLM Quality and Compliance Officer.

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

d. **Special Procedures.** The VA medical facility laboratory must review records at least once every 2 years to verify that procedures are performed in a manner consistent with AABB standards.

(1) **Perioperative Transfusion.** When perioperative autologous procedures are conducted within the VA medical facility but provided by other services in the VA medical facility (e.g., surgery, contract), the VA medical facility Transfusion Medical Director must provide guidance to the service performing the procedure and ensure the procedure is performed in a manner consistent with AABB standards.

(2) **Therapeutic Phlebotomy.**

(a) Therapeutic phlebotomy must only be performed when ordered by a health care provider.

(b) When therapeutic phlebotomy procedures are conducted within the VA medical facility but provided by other services in the VA medical facility (e.g., hematology-oncology), the VA medical facility laboratory must ensure the procedure is documented and performed in a manner consistent with current applicable accreditation standards.

(3) **Therapeutic Apheresis.** When therapeutic apheresis procedures are conducted within the VA medical facility but provided by other services in the VA medical facility (e.g., dialysis, contract), the VA medical facility Transfusion Medical Director or the VA medical facility Chief, PLM must provide guidance to the service performing the procedure to ensure that the procedures are performed in a manner consistent with AABB standards. The procedures must follow 42 C.F.R. § 493.1251(b).

(4) **Human Cells and Tissues.**

(a) For VA medical facility laboratories that have accepted responsibility for the acquisition and storage of human cells, tissues and cellular- and tissue-based products (HCT/Ps), the products must be acquired from approved vendors that meet applicable VA standards and are accredited by AABB, CAP or the Foundation for the Accreditation of Cellular Therapies (FACT). **NOTE:** *HCT/Ps are defined in 21 C.F.R. § 1271.3(d) as articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion or transfer into a human recipient. Examples of HCT/Ps include, but are not limited to, bone, ligament, skin, dura mater, heart valve, cornea, hematopoietic stem/progenitor cells derived from peripheral and cord blood, manipulated autologous chondrocytes, epithelial cells on a synthetic matrix and semen or other reproductive tissue.*

(b) VA medical facilities that store tissue products must ensure the products are acquired from manufacturer's that are registered with the FDA. Accreditation by the American Association of Tissue Banks (AATB) is highly recommended.

(c) The Transfusion Service and the Cellular Therapy service at the VA medical facility must establish mechanisms to capture traceability of the cellular therapy product from acquisition to storage, distribution and final disposition. Standard operating procedures must adhere to either AABB or FACT accreditation standards.

(d) VA medical facility laboratories that perform histocompatibility, immunogenetics and transplantation testing must be accredited by the ASHI.

(e) VA medical facilities that store tissue products or organs must complete the Organ and Procurement Organization (OPO)-Donation after Cardiac Death (DCD) VA medical facility verification at least once a year. **NOTE:** For more information on OPO DCD, see VHA Directive 1102.07, *Organ Donation After Circulatory Death*, dated January 28, 2021. The verification requires:

1. OPO current agreement.
2. DCD procedures.
3. Tissue bank (including eye bank) current FDA registration.

(f) VA medical facilities must complete the SF-523B, Authorization for Tissue Donation, prior to the removal of organ or tissue for donation. All organ or tissue donation activities must be conducted according to VA medical facility procedures.

(g) VA medical facilities that encounter a tissue-associated deviation must submit a Biological Product Deviation Report to FDA and forward a copy to the National PLM Quality and Compliance Officer.

### 13. SURGICAL PATHOLOGY, CYTOPATHOLOGY AND MOHS SURGERY

a. **Anatomic Pathology.** Anatomic pathology includes surgical pathology, cytopathology and autopsy pathology.

(1) Diagnostic services in anatomic pathology must provide complete diagnoses for specimens obtained in the VA medical facilities and outreach functions that meet requirements for offering diagnostic services.

(2) Surgical pathology, autopsy, diagnostic EM, non-GYN cytopathology and abnormal GYN cytopathology examinations and written reports must be provided by VA medical facility pathology physicians, board certified by the American Board of Pathology in Anatomic Pathology. The VA medical facility Chief, PLM or the CLIA Laboratory Director must have a process to assess performance for all individuals performing anatomic pathology activities at VA.

(3) The following exceptions must be made when a VA health care provider is deemed competent by the VA medical facility Chief, PLM and the VA health care provider is privileged within the VA medical facility to provide specific pathology reports within their specialty:

(a) Oral pathology reports must be reported through the LIS pathology package by VA physicians or dentists board-certified in Oral and Maxillofacial Pathology.

(b) Mohs surgery cases must be reported through the LIS pathology package 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; or through an Accreditation Council for Graduate Medical Education fellowship in Micrographic Surgery and Dermatologic Oncology.

(c) Dermatopathology must be reported through the LIS pathology package by non-pathology physicians who are certified by the American Board of Dermatology or American Board of Pathology with fellowship and board certification in dermatopathology.

(d) Neuropathology reports must be reported through the LIS pathology package by non-pathology physicians who are board certified in neuropathology by the American Board of Pathology.

(e) Only hematopathology-fellowship trained pathologists who are clinical pathology board certified may sign out bone marrow, peripheral blood smears and lymph nodes and must ensure sign-out reports are uploaded into the anatomic pathology package.

b. **Surgical Pathology.** VA medical facilities must provide surgical pathology services.

(1) The VA medical facility laboratory must have procedures that addresses a patient request that specimens be returned to them after a surgical procedure. Whenever possible without compromising clinical care, the laboratory must attempt to accommodate the patient's religious needs. The procedures must be approved by the VA medical facility Medical Executive Committee and Office of Regional Counsel.

(2) Specimens must only be released after the final pathology report is signed out and all conditions stated in the specimen release procedures are met.

c. **Review of Outside Pathological Material.**

(1) VA-appointed pathology physicians at the VA medical facility must review all materials and reports and issue a report in the LIS pathology package prior to treatment.

(2) All tissue, foreign bodies and other specimens removed from patients must be referred to VA medical facility PLM for examination, unless specifically exempted by the clinical governing body of the VA medical facility.

(3) Outside tissue slides must be sent to VA medical facility PLM along with form SF-515, Medical Record – Tissue Examination, which must be completed by the patient's

clinical physician. The completed form and slides must be available prior to accessioning, examination and reporting.

d. **Cytopathology.**

(1) The VA medical facility laboratory must provide cytology services either on-site, through contract or sharing agreement.

(2) All cytology specimens obtained at VA medical facilities must be processed through VA medical facility PLM or VA-contracted laboratory for evaluation and diagnosis.

(3) VA medical facilities where screening occurs and where cases are signed out must be accredited for GYN cytopathology.

(4) All screening of VA GYN cytopathology slides must be performed physically in a VA medical facility laboratory.

(5) The cytotechnologist must be an employee of the pathology group providing cytology services for VA.

(6) The name and address of the VA medical facility laboratory where the slide screening occurs must be included in the final report.

(7) Any person who screens GYN cytopathology slides must screen no more than 100 slide equivalents per 24-hour period.

(8) All non-GYN and abnormal GYN cytopathology specimens must be evaluated, diagnosed and verified by a qualified pathology physician.

(9) GYN cytopathology reports must be completed within 14 business days.

(10) Negative GYN cytopathology specimens must be reported by cytotechnologists when:

(a) The cytotechnologist meets the qualifications of 42 C.F.R. § 493.1483.

(b) The VA medical facility CLIA Laboratory Director has certified the competency of the cytotechnologist to release negative GYN cytopathology results by written delegation.

(c) At least 10% of the cytotechnologist's gynecologic cases interpreted as negative must be randomly selected and prospectively rescreened, diagnosed and documented by a qualified VA medical facility pathology physician or qualified cytotechnologist with at least 3 years of full-time (2,080 hours per year) experience as a cytotechnologist within the preceding 10 years.

(d) 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 VA medical facility Chief, PLM.

e. **Mohs Surgery.** Mohs surgery at VA medical facilities must be included as part of the main VA medical facility laboratory accreditation or compliance verification process.

(1) Individuals performing the histopathology for Mohs surgery must meet the requirements in 42 C.F.R. § 493.1449 in addition to:

(a) Board certification in anatomic pathology by the American Board of Pathology; or

(b) Board certification by the American Board of Dermatology with training and competency in Mohs Surgery and frozen section interpretation and diagnosis. Refer to VHA Directive 1101.12 for the approved training requirements and board certifications.

(2) **Mohs Surgery Review.** *NOTE: For detailed information on Mohs surgery, see VHA Directive 1101.12.*

(a) Diagnostic reviews of frozen sections must be documented in the EHR.

(b) Mohs surgery cases must be accessioned and reported in the LIS pathology package. At a minimum, the diagnosis and SNOMED code must be entered and linked to the Mohs surgery case number and location of full report in EHR.

(c) Mohs surgery slides and accompanying information must be stored in compliance with VHA Directive 1101.12. Residual wet tissue must be forwarded to pathology for retention for a minimum of 2 weeks after the case is signed out. **NOTE:** *For more information on records retention guidelines, see Record and Specimen Retention Guidelines, available at: <https://dva.gov.sharepoint.com/sites/VHADiagnosticservices/PLMS/edcen/SitePages/Laboratory-Accreditation.aspx>. This is an internal VA website that is not available to the public.*

(d) VA health care providers who read Mohs surgery frozen sections and are privileged within the VA medical facility to perform Mohs surgery or pathology, must result and release Mohs surgery pathology reports into LIS.

(e) For Mohs surgeries that do not have a previous diagnosis documented in the LIS pathology package, attempts to obtain the prior biopsy must be made and the outside diagnosis reviewed by a VA medical facility pathology physician. A pathology report of the outside case review must be generated and reported in the LIS pathology package.

(f) The VA medical facility CoS must be responsible for ensuring that at least 10% random retrospective second review is performed for all Mohs surgeries. 100% review is performed for any Veteran requiring Mohs surgery in a VA medical facility where the Mohs surgery is performed for which a previous diagnosis is not documented.



**f. Oversight of Pathology.**

VA medical facility laboratories 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) Timely communication of surgical pathology and cytopathology diagnoses (including significant report modifications) to VA health care providers authorized to receive or transmit diagnoses.

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

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

(4) Ongoing competency of the pathology physicians (measured via OPPE) and pathology staff.

**g. Anatomic Pathology Quality Management Program.**

(1) Each VA medical facility must have an anatomic pathology QM Program that mandates participation in an educational program for anatomic pathology external quality review. These programs are arranged and monitored by the Executive Director, PLM.

(a) Staff that report cases, review cases or is involved in pre-screening of cases must participate in quality review programs.

(b) VA medical facility laboratories must establish and monitor the expected turnaround time (TAT) for routine surgical pathology and cytopathology reports. TAT must be defined based on needs and requirements of the VA medical facility and in agreement with VA health care providers.

(2) An anatomic pathology external quality review program must include all the diagnostic activities of anatomic pathology services provided at each VA medical facility and by each health care provider responsible for reporting anatomic pathology material at that VA medical facility.

(3) These programs must:

(a) Be designed to identify deficiencies resulting from inadequate experience, education or training.

(b) Be an element to determine competency of the specific activities performed at a VA medical facility and by a VA health care provider. If the activity is diagnostic, an effective program should be able to identify any inability to recognize and distinguish clinically important diagnostic categories or abnormalities.

(c) The test materials must be evaluated in the routine manner as for patient specimens.

**(4) Anatomic Pathology Internal Quality Review – Second Clinical Review of Cases.**

(a) In VA medical facilities with two or more VA medical facility pathology physicians, second reviews must be arranged within the staff. In cases where a consensus cannot be made, a third opinion must be obtained expeditiously, either from local consultants, such as pathology physicians at an affiliated medical school or from the Joint Pathology Center (JPC), with a request for consultation. If there is a significant change in diagnosis that affects the patient's treatment, the VA medical facility Chief, PLM, must advise the VA medical facility CoS and the patient's VA health care provider who must take action to inform the patient and revise or amend the treatment. The communication of the amended report with the revised diagnosis(es) must be documented in the patient's EHR with read back received. For more information on second opinions, see Guide 6 - Management of Second Opinion Anatomic Pathology Consultations <https://dvagov.sharepoint.com/sites/VHADiagnosticservices/PLMS/edcen/SitePages/Laboratory-Accreditation.aspx>. **NOTE:** This is an internal VA website that is not available to the public.

(b) Every VA medical facility that performs anatomic pathology must have procedures for third-party consultation processes to ensure quality patient care and eliminate conflicts of interest. In this specific context, third party consultation refers to a secondary interpretation not the primary read of a case. Procedures must specify such results and must be sent to the VA medical facility QM Office, the VA health care provider of the record and the VA medical facility Chief, PLM.

(c) VA medical facilities must have OPPE procedures approved by the VA medical facility Medical Executive Committee that meet National PLM Program Office requirements. See Guide 5 – Specific Processes for External OPPE Case Review at <https://dvagov.sharepoint.com/sites/VHADiagnosticservices/PLMS/edcen/SitePages/Laboratory-Accreditation.aspx>. **NOTE:** This is an internal VA website that is not available to the public.

(d) Contract or fee basis pathology physicians who are privileged at the VA medical facility must meet the 10% retrospective OPPE review process. This does not apply to reference laboratory fee for service activities.

**h. Evaluation of Anatomic Pathology Specimens.** At the time of anatomic pathology specimen evaluation, a complete summary of all previous specimens obtained from the patient at the VA medical facility and their diagnosis(es) must be available to aid in interpretation of the current specimen. Relevant clinical history and if available, 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.

i. **Examination of Specimens.**

(1) All specimens, both surgical and cytologic, must be sent to VA medical facility PLM for evaluation by a privileged pathology physician.

(2) Processing and evaluation of specimens must be directed by a qualified and privileged VA medical facility pathology physician.

(3) All tissue and cytology specimens sent to VA medical facility PLM must be accompanied by a complete requisition.

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

(5) If the evaluation of anatomic pathology specimen concludes that there are new malignant diagnoses without definitive prior diagnosis on surgical pathology or cytopathology cases or in cases with unexpected diagnoses of clinical significance:

(a) The results must be communicated to the ordering health care provider within the timeframes specified by the National PLM Program Office, with documentation in the pathology report. For more information on timelines, see Guide 4, New Malignancy Notification Policy, available at:

<https://dvagov.sharepoint.com/sites/VHADiagnosticservices/PLMS/edcen/SitePages/Laboratory-Accreditation.aspx>. **NOTE:** This is an internal VA website that is not available to the public.

(b) Exceptions to the malignancy notification to ordering providers are cutaneous basal cell and squamous cell carcinomas. For further information, see Guide 4, New Malignancy Notification Policy, available at:

<https://dvagov.sharepoint.com/sites/VHADiagnosticservices/PLMS/edcen/SitePages/Laboratory-Accreditation.aspx>. **NOTE:** This is an internal VA website that is not available to the public.

(c) Second pathology physician review of all new malignancies or unexpected diagnoses of clinical significance (with exception of skin squamous cell and basal cell carcinomas) requires documentation in the pathology report or EHR.

j. All frozen section diagnoses that do not agree with the diagnosis on the permanent section must be communicated to the ordering VA health care provider and documented in the patient's pathology report. Refer to paragraph 8 for information on Anatomic Pathology Reporting.

## 14. ELECTRON MICROSCOPY

a. **Diagnostic Electron Microscopy in Laboratory Services.** Diagnostic EM is a method of taking high resolution images of specimens using an electron microscope and is often used for research and diagnostic purposes. The term "Electron Microscopy" refers to the most used modality, Transmission Electron Microscopy, although

laboratories also use Scanning Electron Microscopy and Electron Probe X-ray Microanalysis in diagnostic and research work.

b. Any EM Program must have a quality review process that includes the assessment of diagnostic EM through external evaluation of cases.

## 15. TELEPATHOLOGY

a. VA medical facilities that implement elements of whole slide imaging telepathology must follow Guide 2, Telepathology Statement Policy. Telepathology clinical use may be found at:

<https://dvagov.sharepoint.com/sites/VHADiagnosticservices/PLMS/edcen/SitePages/Telopathology.aspx>. **NOTE:** This is an internal VA website that is not available to this public.

b. All telepathology processes must be validated or verified in accordance with standard regulatory and VA policies for laboratory testing.

## 16. POST-MORTEM EXAMINATION

VA medical facilities must provide post-mortem examination services either on-site or through a contract or sharing agreement. The medical staff must offer and, when appropriate, request authorization for post-mortem examination in all deaths, consistent with the requirements of 38 C.F.R. § 17.170, from the VA medical facility Director for overall management of post-mortem examination services. Findings from post-mortem examinations must be presented to the medical staff once annually. **NOTE:** For further information on post-mortem examinations, see VHA Directive 1601B.04.

a. **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 are also referred to as medical examiner or coroner's cases. These cases must be reported to the appropriate officials and autopsies pursued in accordance with requirements of 38 C.F.R. § 17.170 (b), (c), and (d); 38 U.S.C. §§ 5701(f)(2) and 7332; and the Health Insurance Portability and Accountability Act Privacy Rule.

(1) In cases where the U.S. does not have exclusive jurisdiction over the area where the body was found, the medical examiner or coroner in that area must 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, the VA medical facility Director must request Office of Chief Counsel in the Districts review to ensure that authority exists in all applicable statutes in paragraph 16.a. above, before releasing the information.

(2) Where the U.S. has jurisdiction over the area where the body is found, refer to 38 C.F.R. § 17.170(b).

(3) Office of General Counsel in the Districts Counsel must be consulted if there is any question whether a death will be reported to the local coroner or medical examiner.

**b. Deaths For Which The Joint Pathology Center Has Established War-Related Registries.** Instructions for submitting post-mortem examinations on Veterans belonging to these groups are available on the JPC website at <https://jpc.capmed.mil/>.

**c. 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 VA medical facility pathology physician 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, qualified in anatomic pathology.

(3) There must be a positive identification of the deceased by the VA medical facility pathology physician who checks the name and other identifying data attached to the deceased and compare these with information recorded on SF-523B.

(4) Family's wishes as recorded on the SF-523B must be adhered to.

(5) VA may order an autopsy to be performed only if consent is first obtained as required by 38 C.F.R § 17.170 and under the circumstance defined in VHA Directive 1601B.04.

(6) Universal precautions must be exercised.

(7) 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.

**d. Post-Mortem Examination Reports.**

(1) For autopsies performed at a VA medical facility, a Provisional Anatomic Diagnosis must be released into EHR within 2 business days.

(2) Final post-mortem reports must be coded using SNOMED codes.

(3) The completed post-mortem examination, final anatomic diagnosis, with final copy of succeeding pages, must be made a part of the patient's EHR within 60 business 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) For autopsies performed at a VA medical facility, only a privileged VA medical facility pathology physician, board certified in anatomic pathology, can provide a final written diagnosis for gross and microscopic post-mortem examination findings.

(6) The VA medical facility Chief, PLM, must provide the VA medical facility Medical Executive Committee 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.

(7) Autopsy Reviews conducted at VA medical facilities are considered to be part of the VA medical facility Quality Assurance (QA) program. Only the quality review of autopsy services is covered by 38 U.S.C. § 5705 and its implementing regulations.

**e. Use of Post-Mortem Examination Tissues for Diagnostic, Scientific or Therapeutic Purposes.**

(1) SF-523B makes provision for the removal and retention of tissues for diagnostic, scientific or therapeutic purposes.

(2) Research using tissues or organs removed at autopsy must conform with a written protocol approved by the VA medical facility Research and Development Committee and by its Institutional Review Board before the research begins.

**f. Confidential Treatment of Post-Mortem Examination Records.**

(1) When requests for post-mortem examination records or tissue are received, PLM must follow the VA medical facility Privacy Office procedures for release of information.

(2) If tissues or records are to be sent from a VA medical facility laboratory for examination in community care laboratories or by legal or regulatory 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. §§ 5701 and 7332).

(3) 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 must not disclose any information in an identifiable form without prior specific VA authorization.

(b) Information must be safeguarded from disclosure.

(c) The slides and records must be returned to VA when the recipients' studies are complete.

## 17. JOINT PATHOLOGY CENTER REFERENCE LABORATORY SERVICES

a. **Scope.** VA medical facility laboratories where surgical specimens are examined must participate in the JPC Consultation and Registry Program.

b. **Joint Pathology Center Registries.** Routine contributions of surgical and autopsy specimens to the JPC war-related Special Registries (e.g., Prisoner of War, Radiation, Agent Orange, Gulf War) are not for diagnosis, but in order to enhance the research value of these repositories. VA cooperates fully to provide any pathologic specimens for any appropriately approved, collaborative research project between JPC and VA. Unless specifically requested, routine diagnostic consultative reports from JPC for these contributed cases are not sent back to VA and are archived indefinitely at JPC.

## 18. TRAINING

There are no formal training requirements associate with this directive.

## 19. RECORDS MANAGEMENT

All records regardless of format (for example, paper, electronic, electronic systems) created by this directive must be managed as required by the National Archives and Records Administration (NARA) approved records schedules found in VHA Records Control Schedule 10-1. Questions regarding any aspect of records management can be addressed to the appropriate Records Officer.

## 20. BACKGROUND

a. In 1988, Congress passed CLIA as part of the Public Health Service Act (42 U.S.C. § 263(a)). These amendments codified into law requirements for the staffing, management, procedures and oversight of 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 42 C.F.R. part 493.

b. In May 2021, VA published 38 C.F.R. § 17.3500 regarding VA application of 42 C.F.R. part 493 standards after consultation with HHS, as required by statute. Enforcement procedures for subpart R of 42 C.F.R. part 493 can be found under 38 C.F.R. § 17.3500(m).

c. NEO is a division under PLM and has a legislated responsibility to oversee and enforce CLIA to ensure the quality of services provided by VA clinical laboratories comply with regulatory, accreditation and policy guidelines. PLM NEO is staffed with VA Central Office staff, National PLM Quality and Compliance Agents and the National PLM Quality and Compliance Officer. The National PLM Quality and Compliance Officer provides leadership and direction for PLM NEO under the guidance of the Executive Director, PLM.

d. PLM provides the principal medical diagnostic laboratory testing and transfusion functions in 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. PLM is responsible for the creation and enforcement of VA-specific laboratory standards. The National PLM Program Office establishes national policies applicable to VA clinical laboratories. In addition, the National PLM Program Office provides PLM guidance to senior leadership in the laboratory community in general, to help ensure that timely, cost effective, and high-quality anatomic and clinical pathology services are provided for both patients and caregivers.

e. At defined intervals, accrediting, compliance and regulatory agencies summarize and submit the findings of their inspection and accreditation or compliance verification processes to PLM NEO and to the individual VA medical facilities.

## 21. DEFINITIONS

a. **Alternative Proficiency Testing.** Alternative PT are the alternate methods for laboratory testing used when the formal proficiency assessment for the testing is not available.

b. **Ancillary Testing.** Ancillary testing is laboratory testing performed under the administration of the VA medical facility, either within or outside the physical facilities of the main VA medical facility laboratory. This includes all VA medical facility laboratories, such as bedside testing, satellite or specialty laboratories, contracted and non-contracted CBOC testing sites, HBHC, mobile clinics and testing performed at health fairs or stand-downs. Ancillary testing includes all VA medical facility laboratories that fall under the auspices of the main VA medical facility laboratory even when they are under a separate VA medical facility CLIA Laboratory Director, CLIA registration number or separate accreditation. ***NOTE: Point of care testing is considered part of ancillary testing.***

c. **Autopsy.** Autopsy is the post-mortem examination to compare pre-mortem diagnoses and diagnostic assessment procedures to confirm the cause of death or the extent of disease. The autopsy report is part of the EHR and is not 38 U.S.C. § 5705 protected.

d. **Autopsy Review.** Autopsy review is the post-mortem examination to compare pre-mortem diagnoses and diagnostic assessment procedures with post-mortem diagnoses and other autopsy findings to assess diagnostic accuracy. The quality review of autopsy services is covered by 38 U.S.C. § 5705 and its implementing regulations. See VHA Directive 1320, Quality Management and Patient Safety Activities That Can Generate Confidential Records and Documents, July 10, 2020, for additional information.



e. **Current Procedural Terminology Codes.** CPT codes are a list of descriptive terms and identifying codes for reporting medical services and procedures performed by VA health care providers. The terminology provides a uniform language to accurately describe medical, surgical and diagnostic services and provides means for uniform nationwide communication among health care providers, patients and third parties. CPT codes are maintained and copyrighted by the American Medical Association.

f. **Electronic Health Record.** EHR is the digital collection of patient health information resulting from clinical patient care, medical testing and other care-related activities. Authorized VA health care provider may access EHR to facilitate and document medical care. EHR comprises existing and forthcoming VA software including Computerized Patient Record System (CPRS), Veterans Information Systems and Technology Architecture (VistA) and Cerner platforms. **NOTE:** *The purpose of this definition is to adopt a short, general term (EHR) to use in VHA national policy in place of software-specific terms while VA transitions platforms.*

g. **Focused Professional Practice Evaluation.** FPPE is an oversight process within a defined period of evaluation whereby the respective clinical service chief and the Executive Committee of the Medical Staff (ECMS) evaluates the privilege-specific competence of a licensed independent health care practitioner (LIP) who does not yet have documented evidence of competently performing the requested privileges at the VA medical facility. This is a routine process with standardized criteria approved by the VA medical facility's ECMS and Director and applied to LIPs within the same specialty who hold the same privileges. **NOTE:** *For further information on FPPE, see VHA Directive 1100.21(1), Privileging, dated March 2, 2023.*

h. **High Complexity Testing.** High complexity testing is the most complicated type of laboratory test, requiring the most rigid testing requirements outlined in the CLIA regulations. Test complexity is determined by the FDA according to the criteria outlined in the 42 C.F.R. §§ 493.17(a) and 493.25.

i. **Histocompatibility.** Histocompatibility is the examination of human leukocyte antigens in a patient, often referred to as tissue typing or genetic matching. Histocompatibility is performed for all donors and recipients in solid organ or bone marrow transplantation to help match the donor with the most suitable recipients to decrease the likelihood of organ transplant rejection.

j. **Home-Based Health Care.** HBHC is laboratory testing performed in the patient's home by VA and VA-contracted employees under VA home-based programs.

k. **Laboratory Developed Test.** A Laboratory Developed Test (LDT) is an in vitro diagnostic test that is manufactured by and used within a single laboratory (i.e., a laboratory with a single CLIA certificate). LDTs are also sometimes called in-house developed tests or "home brew" tests. CLIA prohibits the release of any test results prior to the laboratory establishing certain performance characteristics relating to analytical validity for the use of that test system in the laboratory's own environment. See 42 C.F.R. § 493.1253(b)(2).

l. **Laboratory Information System.** LIS is a software system that records, manages and stores data for VA medical facility laboratories. LIS sends laboratory test orders to laboratory instruments, tracks those orders and records the results to a searchable database.

m. **Laboratory Test.** A laboratory test is an examination, diagnostic or monitoring procedure on a human specimen for the purposes of diagnosis, prevention or treatment of disease or assessment of a medical condition.

n. **Moderate Complexity Testing.** Moderate complexity testing is the rating given by FDA to commercially marketed in vitro diagnostic tests based on their risk to public health. The complexity is determined based on the scoring criteria outlined in 42 C.F.R. §§ 493.17 and 493.20.

o. **Mohs Surgery.** Mohs surgery is a precise surgical procedure for microscopically controlled removal of skin tumor that is used to treat skin cancer. During Mohs surgery, thin layers of cancer-containing skin are progressively removed and examined until only cancer-free tissue remains.

p. **Non-Regulated Analyte.** A non-regulated analyte is an analyte not defined as requiring PT in 42 C.F.R. part 493 Subpart I.

q. **Non-Waived Testing.** Non-waived testing is laboratory tests categorized as moderate complexity, PPM, or high complexity by FDA according to their scoring system.

r. **Outreach Functions.** Outreach functions are the coordination and provision of clinical services in an outreach setting to bring primary health care directly to communities that may otherwise face barriers in seeking and accessing care at fixed health center sites. Clinical outreach is an approach for individuals and communities to obtain laboratory services outside the acute care setting.

s. **Ongoing Professional Practice Evaluation.** OPPE is the ongoing monitoring of privileged LIPs to identify clinical practice trends that may impact the quality and safety of care. OPPE applies to all LIPs who are privileged as well as physician assistants, nurse practitioners and clinical pharmacy specialists who are on Scopes of Practice. Information and data considered must be LIP and specialty specific. The OPPE data is maintained as part of the Practitioner Profile to be analyzed in the VA medical facility's ongoing monitoring program. ***NOTE: Though not privileged, occupations which must be credentialed through the medical staff process must be monitored through the FPPE and OPPE process. The respective service chief must maintain a Practitioner Profile on these LIPs. These occupations include, but may not be limited to, clinical pharmacy specialists, physician assistants, and nurse practitioners on Scopes of Practice. For more information on VHA Pathology OPPE standards, see VHA Memorandum 2022-03-40, Updated Pathology Quality Review Requirements for Facilities Implementing New Pathology Ongoing Professional Practice Evaluation (OPPE) Standards (VIEWS***

7004869), dated March 8, 2022 or current version. For further information on OPPE, see VHA Directive 1100.21(1).

t. **Patient Self-Testing.** Patient self-testing is the use by patients or their caregivers of a device and related supplies that are approved by FDA for home use in order to perform laboratory testing. Patient self-testing is considered an alternative testing method for patients who are suitably selected and trained. Patient self-testing is not considered a laboratory test.

u. **Point of Care Testing.** Point of care testing are tests designed to be used at or near the site where the patient is located and are performed outside the physical facilities of the clinical laboratory. Point of care testing might mistakenly be confused with waived testing. Point of care testing can be part of ancillary testing. These terms do not relate directly to test complexity and it cannot be assumed that a test system is waived simply because it is performed at the point of care.

v. **Privileged Provider.** For purposes of this directive, a privileged provider is a VA health care provider who meets the personnel qualifications for provider performed microscopy (PPM) as defined in the CLIA regulations, 42 C.F.R. § 493.1363, and is privileged by the VA medical facility to perform laboratory testing as part of their clinical scope of practice.

w. **Proficiency Testing.** PT is the testing of unknown samples sent to a laboratory by an HHS-approved PT program. PT is used by PLM NEO to routinely monitor the laboratory's performance. Proficiency testing is a program in which samples 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 CLIA program.

x. **Proficiency Testing Challenge.** A PT challenge is an unknown sample in a PT shipment. One to five PT challenges are usually included in a PT event for each analyte.

y. **Proficiency Testing Event.** A PT 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 PT challenges for each analyte. There may be multiple PT kits per PT event. Each PT kit is tracked separately.

z. **Proficiency Testing Kit.** A PT kit is a set of PT challenges packaged together and used to monitor test performance for specific analytes.

aa. **Proficiency Testing Survey.** A PT survey is a survey sent to a VA medical facility to assess that laboratory's analysis with results comparative to those of its peers.

bb. **Provider-Performed Microscopy Testing.** PPM testing is 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 VA health care provider's own patient.

cc. **Reference Laboratory.** A reference laboratory is a large laboratory that performs testing not usually performed in a hospital laboratory or any laboratory that received specimens from another laboratory for analysis.

dd. **Regulated Analyte.** Regulated analyte is an analyte requiring PT as defined in 42 C.F.R. part 493 subpart I.

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

ff. **Systemized Nomenclature of Medicine.** SNOMED is a coding standard that contains a hierarchical listing of terms that define or describe patient condition, disease or specimen types submitted for analysis. Standardized SNOMED codes are used for data retrieval.

gg. **Telepathology.** Telepathology is the practice of remote pathology using telecommunication links to enable transmission of digital pathology images for primary diagnosis, QA and OPPE, digital tumor boards, education, research, or second opinion diagnoses.

hh. **Tissue.** A tissue is a group of functional cells or intercellular matrix intended for implantation, transplantation or other therapy (e.g., cornea, ligaments, bone). Examples of tissues that can be transplanted are blood, bones, bone marrow, corneas, heart valves, ligaments, saphenous veins and tendons. Cellular therapy products covered by the AABB Standards for Cellular Therapy Services are not included herein.

ii. **Validation.** Validation is the process of establishing recorded evidence that provides assurance that a specific process consistently produces an outcome meeting predetermined specifications and quality attributes.

jj. **Verification.** Verification is the confirmation by examination and provision of objective evidence that specified requirements are met.

kk. **Waived Testing.** Waived testing are tests categorized as simple laboratory examinations and procedures that have an insignificant risk of an erroneous result. The complexity is determined by FDA and outlined in 42 C.F.R. § 493.17.

## 22. REFERENCES

- a. P.L. 100-578.
- b. P.L. 102-139.
- c. 38 U.S.C. §§ 5701, 5705 and 7332.
- d. 42 U.S.C. § 263.
- e. 21 C.F.R. § 1271.3.

- f. 38 C.F.R. §§ 17.170 and 17.3500.
- g. 42 C.F.R. parts 73 and 493.
- h. VHA Directive 1043, Restructuring of VHA Clinical Programs, dated September 2, 2016.
- i. VHA Directive 1050.01, VHA Quality and Patient Safety Programs, dated March 24, 2023.
- j. VHA Directive 1100.21(1), Privileging, dated March 2, 2023.
- k. VHA Directive 1101.12, Mohs Micrographic Surgery, dated January 27, 2023.
- l. VHA Directive 1102.07, Organ Donation After Circulatory Death, dated January 28, 2021.
- m. VHA Directive 1131, Management of Infectious Diseases and Infection Prevention and Control Programs, dated November 27, 2023.
- n. VHA Directive 1138, Patient Self-Testing for Monitoring of Prothrombin Time International Normalized Ratio in Patients on Warfarin Anticoagulation Therapy, dated January 27, 2023.
- o. VHA Directive 1320, Quality Management and Patient Safety Activities That Can Generate Confidential Records and Documents, dated July 10, 2020.
- p. VHA Directive 1601B.04, Decedent Affairs, dated December 1, 2017.
- q. VHA Directive 1907.01(1), VHA Health Information Management and Health Records, dated April 5, 2021.
- r. General Services Administration. SF-515, Medical Record – Tissue Examination. Available at: <https://www.gsa.gov/reference/forms>.
- s. General Services Administration. SF-523B, Authorization for Tissue Donation. Available at: <https://www.gsa.gov/reference/forms>.
- t. VHA Memorandum 2022-03-40, Updated Pathology Quality Review Requirements for Facilities Implementing New Pathology Ongoing Professional Practice Evaluation (OPPE) Standards (VIEWS 7004869), dated March 8, 2022.
- u. PLM. Anatomic Pathology. <https://dvagov.sharepoint.com/sites/VHADiagnosticservices/PLMS/edcen/SitePages/Document-Library.aspx>. **NOTE:** This is an internal VA website that is not available to the public.
- v. PLM. Guide 11 – BSL-3 Laboratory Risk Assessment Tool. <https://dvagov.sharepoint.com/sites/VHADiagnosticservices/PLMS/edcen/SitePages/La>

[boratory-Accreditation.aspx](#). **NOTE:** This is an internal VA website that is not available to the public.

w. PLM. Guide 2 - Telepathology Statement Policy.

<https://dvagov.sharepoint.com/sites/VHADiagnosticservices/PLMS/edcen/SitePages/Laboratory-Accreditation.aspx>. **NOTE:** This is an internal VA website that is not available to the public.

x. PLM intranet website: <https://vaww.lab.med.va.gov/index.asp>. **NOTE:** This is an internal VA website that is not available to the public.

y. PLM. OPPE Guide 3.

<https://dvagov.sharepoint.com/sites/VHADiagnosticservices/PLMS/edcen/SitePages/Laboratory-Accreditation.aspx>. **NOTE:** This is an internal VA website that is not available to the public.

z. PLM. Guide 5 - Specific Processes for External OPPE Case Review.

<https://dvagov.sharepoint.com/sites/VHADiagnosticservices/PLMS/edcen/SitePages/Laboratory-Accreditation.aspx>. **NOTE:** This is an internal VA website that is not available to the public.

aa. PLM. Guide 6 - Management of Second Opinion Anatomic Pathology Consultations.

<https://dvagov.sharepoint.com/sites/VHADiagnosticservices/PLMS/edcen/SitePages/Laboratory-Accreditation.aspx>. **NOTE:** This is an internal VA website that is not available to the public.

bb. PLM. New Malignancy Notification Policy.

<https://dvagov.sharepoint.com/sites/VHADiagnosticservices/PLMS/edcen/SitePages/Laboratory-Accreditation.aspx>. **NOTE:** This is an internal VA website that is not available to the public.

cc. PLM. Record and Specimen Retention Guidelines.

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