

## **PATHOLOGY AND LABORATORY MEDICINE SERVICE PROCEDURES**

- 1. REASON FOR ISSUE.** This Veterans Health Administration (VHA) Handbook is issued to provide procedures for the administration, accreditation, staffing, and functioning of clinical and anatomic pathology laboratories in Department of Veterans Affairs (VA) facilities or facilities managed by VA.
- 2. SUMMARY OF CONTENTS.** This Handbook contains implementation instructions for VHA Directive 1106 and procedures for the administration, accreditation, staffing, and functioning of clinical and anatomic pathology laboratories in VA facilities or managed by VA facilities.
- 3. RELATED ISSUES.** VHA Directive 1106.
- 4. RESPONSIBLE OFFICE.** The Office of Patient Care Services, Diagnostic Services Strategic Health Care Group (115), is responsible for the contents of this Handbook. Questions may be addressed to (202) 461-7357.
- 5. RESCISSIONS.** VHA Handbook 1106.1, dated June 4, 2003, and VHA Handbook 1106.2 dated May 4, 2004, are rescinded.
- 6. RECERTIFICATION:** This VHA Handbook is scheduled for recertification on or before the last working day of October 2013.

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Under Secretary for Health

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## **PATHOLOGY AND LABORATORY MEDICINE SERVICE PROCEDURES**

### **1. PURPOSE**

This Veterans Health Administration (VHA) Handbook provides procedures for the administrative structure and management of services and service lines providing laboratory testing in Department of Veterans Affairs (VA) facilities and their outreach functions. The Handbook further defines requirements unique to VA.

### **2. BACKGROUND**

a. In 1988, Congress passed the Clinical Laboratory Improvement Amendments (CLIA '88) as part of the Public Health Services Act (Title 42 United States Code (U.S.C.) 263a). This amendment codified into law requirements for the staffing, management, procedures and oversight of United States (U.S.) laboratories that perform testing used in the diagnosis, treatment and prevention of disease in patients. The Department of Health and Human Services (HHS) then published implementing regulations for CLIA '88, under Title 42, Code of Federal Regulations (CFR) Part 493.

b. In 1992, Congress passed Public Law (Pub. L.) 102-139, Sec. 101(a), which exempted VHA from CLIA '88 and stated that the Secretary of Veterans Affairs would, in consultation with the Secretary of HHS, publish regulations that would “establish standards equal to that applicable to other medical facility laboratories in accordance with the requirements of Section 353(f) of the Public Health Services Act.”

***NOTE:** This requires VA laboratories to meet the requirements of CLIA '88, but left the enforcement and oversight of the regulations to VA.*

c. The CLIA regulations (42 CFR 493) have been and continue to be modified over time. Rather than revising and publishing VA regulations so that they are equal to 42 CFR 493, this Handbook substitutes 42 CFR 493 for those areas where VA regulations do not provide explicit guidance.

### **3. SCOPE OF LABORATORY TESTING**

a. Pathology and Laboratory Medicine Service provides the principal medical diagnostic laboratory testing and transfusion functions in all VA medical centers and sets the standards for quality, test methods, and procedures for laboratory testing for patient care in the medical center and supported clinics.

b. All laboratory testing within VA used for the diagnosis, treatment, and prevention of disease in patients must be provided in compliance with the procedures outlined in this Handbook and meet the requirements of 42 CFR 493, CLIA '88. Laboratory testing, where applicable, must also meet the requirements of the following organizations:

- (a) The Joint Commission;

- (b) College of American Pathologists (CAP);
- (c) American Association of Blood Banks (AABB);
- (d) Food and Drug Administration (FDA);
- (e) Occupational Safety and Health Administration (OSHA); and
- (f) Nuclear Regulatory Commission (NRC).

c. All laboratory testing, regardless of location, must undergo an on-site inspection by an approved accrediting agency.

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

(2) Sites that perform only tests categorized as waived or provider-performed microscopy (PPM) procedures may be inspected as a part of the main laboratory LAP or may optionally be accredited and inspected as a part of the main facility accrediting process. Reaccreditation inspections for these sites must be conducted as required by the respective accrediting agency. The decision as to whether these testing sites need to be included under the LAP, or as part of the facility accreditation process, must be made in consultation with the Chief or Director of Pathology and Laboratory Medicine Service, the medical staff, and senior leadership within the individual facility.

***NOTE:** The PPM category of testing is exclusively for physicians, dentists, nurse practitioners and midwives, and physician assistants performing the test as part of a patient examination. If PPM procedures are performed by anyone other than this select group of providers, then the procedure is classified as moderately complex and those requirements apply.*

(3) All testing, regardless of complexity level or where it is performed, is under the direct or indirect oversight of the Chief or Director, Pathology and Laboratory Medicine Service.

(a) Direct oversight by the Chief or Director of Pathology and Laboratory Medicine is required for all testing performed under the Medical Center and Community-based Outpatient Clinic (CBOC) laboratory CLIA number(s). Testing under direct oversight of the Chief or Director of Pathology and Laboratory Medicine typically includes all testing performed under the laboratory's accreditation umbrella. Direct oversight is required for all ancillary testing performed by non-providers.

(b) Indirect oversight by the Chief or Director of Pathology and Laboratory Medicine is provided when the organization chooses to remove waived or PPM testing performed by providers from underneath the accreditation umbrella of the laboratory. These testing sites must obtain their own separate VA CLIA numbers issued through the Pathology and Laboratory

Medicine Service National Enforcement Office located in Washington, DC. While the Chief or Director, Pathology and Laboratory Medicine Service is not directly responsible for the results released by the provider, such as might be found at some PPM sites, the Chief or Director, Pathology and Laboratory Medicine must provide guidance for performing these laboratory procedures and ensure that they are carried out in compliance with 42 CFR 493 and current VHA policies. *NOTE: Minimal testing guidance for all laboratory procedures within VHA is provided in Paragraph 7. However, these are minimum requirements and when the requirements of the accrediting agency are more stringent, the more stringent requirements apply.*

(4) All independently accredited VHA laboratories, including CBOC sites performing waived and PPM testing, must be assigned CLIA numbers as outlined in the Interagency Agreement between CMS and VA.

d. The main clinical laboratory in each VHA health care network and each medical center must be directed by a Chief or Director, Pathology and Laboratory Medicine Service, who is a licensed pathologist and board certified in pathology by the American Board of Pathology. The clinical laboratory and anatomic pathology services are under the direction of the Chief or Director, Pathology and Laboratory Medicine Service. *NOTE: No Chief or Director may direct more than five laboratories that perform PPM, moderate or higher complexity testing as defined by CMS.*

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

e. For the previously described laboratory sites that fall outside the accreditation umbrella of the main laboratory, a non-pathologist physician or doctoral scientist may be appointed to serve as the chief or medical director (laboratory director). This individual must be qualified by virtue of documented training, expertise, and experience in the areas of analytical testing, and biological, chemical, or clinical science specifically related to the laboratory testing site's special testing functions. This individual must meet the laboratory director qualifications required by 42 CFR 493.

f. The applicable requirements of 42 CFR 493 and appropriate accreditation standards must be met for any laboratory services offered within a VA medical facility and outreach clinics, regardless of the physical relationship to the main Pathology and Laboratory Medicine Service, or the administrative service assigned to direct the personnel, research, or technical aspects of the test site.

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

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

#### 4. QUALIFICATIONS, ROLE, AND RESPONSIBILITIES OF THE CHIEF OR DIRECTOR, PATHOLOGY AND LABORATORY MEDICINE SERVICE

a. **Qualifications.** The Chief or Director, Pathology and Laboratory Medicine Service, must possess a broad knowledge of clinical medicine, basic medical sciences, clinical laboratory sciences, and management operations. This individual must have the appropriate training and background to meet the requirements of 42 CFR 493.1443 and must be able to discharge the responsibilities cited in 42 CFR 493.1445 and this Handbook.

b. **Role.** *NOTE: The Facility Director is responsible for ensuring that the Chief or Director, Pathology and Laboratory Medicine Service, is appointed as a voting member to the Clinical Executive Board, or analogous medical staff committee.*

(1) The Chief or Director and staff pathologists of Pathology and Laboratory Medicine Service provide consultation and guidance to health care providers regarding matters pertaining to pathology and laboratory medicine and the medical significance of laboratory findings. The scientist(s) in clinical areas and medical technologists provide consultation on laboratory technical findings to patient care personnel according to local policies established by each VA medical center. The Chief or Director, Pathology and Laboratory Medicine Service, designates, in writing, who is qualified to perform consultation and to place medical diagnoses and information in a patient's records.

(2) The Chief or Director, Pathology and Laboratory Medicine Service, or designee, participates in applicable cross-organizational performance-improvement activities, develops and communicates objectives, and coordinates efforts to integrate patient care and support services.

(3) The Chief or Director, Pathology and Laboratory Medicine Service, provides educational direction for the medical and laboratory staff and participates in educational programs of the institution as appropriate. *NOTE: This education may also involve many levels, including medical students, allied health students, graduate students, and residents from academic affiliates.*

c. **Responsibilities.** The Chief or Director, Pathology and Laboratory Medicine Service, is responsible for:

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

(2) Establishing a laboratory management data collection system, using Veterans Health Information Systems and Technology Architecture (Vista) or other approved management systems.

(3) Identifying all testing performed within the facility and its outreach clinics, and to provide assistance and oversight to ensure that any testing performed is in compliance with 42 CFR 493 and VHA policies to include oversight responsibility for Ancillary Testing Sites, and participating in the evaluation of test appropriateness for the institution regardless of the testing site.

(4) Oversight for Ancillary Testing Sites. **Ancillary Testing** encompasses or includes all laboratory testing sites that are outside of the physical limits or physical address of the main VA medical facility's Pathology and Laboratory Medicine Service and also includes all testing sites that fall under the auspices of the main parent facility even when they may be under a separate laboratory director, CLIA registration number, or separate accreditation. Point of Care Testing (POCT) and Home-based Health Care (HBHC) when such testing is performed by a VA employee or a contracted service employee in a patient's home is also included.

(a) In Ancillary Testing Sites that fall outside of the accreditation umbrella of the main laboratory, a non-pathologist physician or doctoral scientist may serve as the chief or medical director. This individual must meet the laboratory director requirements for the appropriate complexity of testing as stated in 42 CFR 1406 and 42 CFR 1443 and be qualified by virtue of documented training, expertise, and experience in the areas of analytical testing, and biological, chemical or clinical science specially related to the Ancillary Testing Site's special testing functions. *NOTE: A separate CLIA certificate is also required for each separately-accredited test site. In such sites, the Chief of Pathology and Laboratory Medicine serves as a consultant to ensure testing is in compliance with VA policies, that good testing practices are utilized; and the Chief of Pathology and Laboratory Medicine is not directly responsible for results reported.*

(b) All testing performed by providers (physicians, dentists, nurse practitioners, midwives, and physician assistants) must be limited to those procedures classified as waived or PPM procedures and must be carried out under the indirect oversight of the Chief or Director, Pathology and Laboratory Medicine Service. The Chief or Director, Pathology and Laboratory Medicine Service, is not directly responsible for the results of laboratory tests performed by the providers, but does have a responsibility to ensure that the tests are being performed in accordance with 42 CFR 493 and existing VHA policy (see subpar. 7e). Every VHA facility must have a mechanism in place, such as a protocol approved by the medical staff, that ensures providers identified by the Chief or Director, Pathology and Laboratory Medicine Service, as failing to follow these testing requirements are not allowed to continue performing laboratory tests on patients.

(c) A provider must also be privileged to perform the specific PPM and waived procedures (e.g., fecal occult blood, urine dipstick testing, etc.) that are appropriate and performed within the provider's specialty. A provider cannot be privileged to perform a blanket category of procedures such as waived procedures. *NOTE: Hereafter, the term "privileged provider" is used to designate this group of specifically-privileged providers.*

(d) All testing performed by non-providers must be carried out under the direct oversight of the Chief or Director, Pathology and Laboratory Medicine Service.

(5) Acting as a consultant for the medical center whenever a non-VA provider is contracted to perform laboratory testing for veterans at a satellite clinic. Documentation must be provided to ensure that the contracted laboratory is appropriately CLIA '88 certified, and all test results are entered into the laboratory module of VistA. *NOTE: This would not apply to testing that is ordered by a non-VA provider and used by a VA provider to treat or monitor a VA patient, as might be the case for shared or co-managed patients. In that case, the results and all appropriate information (e.g., reference range, name of testing laboratory, etc.) need to be included in a Progress Note, included in the paper medical record, or scanned into the patient's electronic medical record as a Note. Only laboratory results that are ordered by a VA provider and tested by a VA laboratory, VA-contracted laboratory, or agent of the VA laboratory are to be entered into the laboratory module of VistA or approved-laboratory software.)*

(6) Providing, for all Ancillary Testing Sites, signatory support for legal medical interpretive reporting when the Chief or Director of the Ancillary Testing Site is a doctoral scientist. The VA medical center's Ancillary Testing Coordinator or other staff appointed by the Laboratory Director must provide quality improvement oversight in each and every Ancillary Testing Site.

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

(8) Managing data and trend analysis. All laboratories performing moderate or high complexity testing must participate in the VA Laboratory Management Information Program (LMIP) or any other management information program designated as the VA national laboratory program.

d. **Delegation of Responsibilities.** The Chief or Director, Pathology and Laboratory Medicine Service, need not perform all responsibilities personally. Selected administrative functions may be delegated to qualified clinical scientists, laboratory managers, and supervisors. Medical care responsibilities may only be delegated to physicians. Technical responsibilities may be delegated to qualified laboratory personnel, as appropriate. The Chief or Director, Pathology and Laboratory Medicine Service, however, remains responsible for the overall operation and administration of the laboratory, ensuring that quality patient services are provided and that personnel operations and laboratory management are run smoothly and efficiently.

e. **Exception (the use of Consulting Pathologists).** If the Chief or Director, Pathology and Laboratory Medicine Service, is not a board-certified pathologist the services of a consulting pathologist must be retained.

(1) In a very small or remotely located VA medical center, or in any VA medical center where a pathologist cannot be successfully recruited, or there is not enough surgical pathology or cytopathology workload to justify a full-time or part-time surgical pathologist in the laboratory, the services of a board-certified, qualified, licensed consulting pathologist must be retained to serve as the laboratory director. This consulting pathologist must ensure the laboratory director responsibilities are discharged as cited in 42 CFR 493.1445.

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

(b) The consultant must play an active role in the educational and staff competency programs of the laboratory and of the institution.

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

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

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

## **5. CATEGORIZATION OF SPECIFIC LABORATORY TEST SYSTEMS, ASSAYS AND EXAMINATIONS BY COMPLEXITY**

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

a. CLIA'88 and its implementing regulations categorize specific laboratory test systems, assays, and examinations by complexity. VHA generally recognizes the complexity level for these laboratory procedures as listed in 42 CFR 493, but requires certain minimal standards be met for performing and documenting these procedures.

b. Minimal testing guidance for all laboratory procedures within VHA is provided in Paragraph 7. In addition, all testing within VHA is subject to inspection and accreditation, and such testing must be performed in compliance with any standards defined by the relevant accrediting organization.

c. According to 42 CFR 493, tests not categorized by the Centers for Disease Control and Prevention (CDC) are considered to be highly complex. Any deviation from the manufacturer's guidance or VHA policy for performing the procedure must also result in the procedure being classified as highly complex.

## **6. TESTING PERSONNEL**

a. Individuals performing laboratory testing must meet the personnel requirements as defined in 42 CFR 493. Furthermore, any non-providers who perform laboratory procedures may only do so under the Ancillary Testing Site program and direct oversight of the Chief or Director, Pathology and Laboratory Medicine Service.

b. Privileged providers performing testing under the main laboratory's accreditation umbrella, may do so only under the ancillary testing program.

c. When waived or PPM testing is performed by privileged providers that is not included under the laboratory accreditation umbrella, the testing site must comply with all requirements as listed in paragraph 7.

## 7. QUALITY IMPROVEMENT

### a. Scope

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

(2) The VA medical center must provide an ongoing, comprehensive continuous Quality Improvement Program under the direction of the Chief or Director, Pathology and Laboratory Medicine Service, which:

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

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

(c) Documents all quality improvement activities.

(3) There must be an on-going, planned, systematic, and objective process for the monitoring and evaluation of the quality improvement plan, and the appropriateness of patient care provided by Pathology and Laboratory Medicine Service.

### b. Inspection and Accreditation

(1) The Chief or Director, Pathology and Laboratory Medicine Service, must ensure current accreditation of all testing sites that perform laboratory tests for patient care by the appropriate, nationally recognized CMS "deemed" accrediting bodies. *NOTE: Primary accreditation and biennial inspection must be coordinated under the nationwide contract initiated by the National Director, Pathology and Laboratory Medicine Service, or the Chief Officer, Policy, Planning and Performance.*

(2) All VA laboratories are required to register with the Pathology and Laboratory Medicine Service National Enforcement Office and be issued a CLIA '88 number.

(a) Each VA facility-based and independently accredited outpatient clinic laboratory must be issued a separate CLIA '88 number.

(b) All Ancillary Testing Sites under the accreditation umbrella of the main laboratory must be included under the main laboratory CLIA '88 registration.

(c) The organization can choose to remove waived testing or PPM testing performed by privileged providers from under the jurisdiction of the laboratory accreditation umbrella. If that option is elected however, these sites must register with the Pathology and Laboratory Medicine Service National Enforcement Office for a waived or PPM CLIA'88 certificate.

(d) VHA facilities are required to revalidate their CLIA'88 certificate with the Pathology and Laboratory Medicine Service National Enforcement Office every 2 years.

(3) Testing sites outside the physical limits of the main VA medical laboratory facilities, including those performing Mohs' surgery, are to be included as part of the main laboratory accrediting process, or must maintain current accreditation by an appropriate, nationally recognized, CMS "deemed" accrediting body in compliance with CLIA'88, Title 42 CFR 493.

*NOTE: VA medical centers are strongly encouraged to also apply for institutional membership in AABB, a nationally recognized professional organization, actively engaged in improving blood banking through educational and accreditation programs.*

(4) The Chief or Director, Pathology and Laboratory Medicine Service, that has a blood bank or transfusion service, must ensure current inspection and accreditation of the facility with AABB if any of the following criteria are met:

(a) Has six or more full-time equivalent (FTE) employees dedicated to the blood bank section.

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

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

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

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

*NOTE: The costs of membership, or alternatively of accreditation and biennial inspection, must be borne by the facility.*

(5) The Chief or Director, Pathology and Laboratory Medicine Service, is mandated to participate in the annual registration and FDA inspection if the facility draws or prepares components or provides transfusion services.

(6) The Chief or Director, Pathology and Laboratory Medicine Service, is responsible for ensuring that all laboratories performing patient care testing meet requirements for hospital accreditation.

(7) On a periodic basis, accrediting and regulatory agencies summarize and submit the findings of their inspection and accreditation processes to the Pathology and Laboratory Medicine Service National Enforcement Office, the VA Pathology Regional Commissioners, and to the individual facilities.

(8) The National Director, Pathology and Laboratory Medicine Service, VHA Central Office, provides oversight responsibility to ensure:

(a) Current accreditation with each of the aforementioned groups and agencies. In those instances where problems having a potential for adverse patient outcome are identified and require corrective action, the Pathology and Laboratory Medicine Service National Enforcement Office works with the Pathology Regional Commissioner, and the Chief or Director, Pathology and Laboratory Medicine Service, at the facility to ensure that corrective action is implemented in a timely manner.

(b) That the required accreditation programs are fully implemented.

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

**c. Required Elements for Quality Improvement in Laboratory Services and Ancillary Testing Sites**

(1) **Quality Improvement Requirements.** With the exception of tests classified as waived or PPM and performed by appropriately privileged providers, the Chief or Director, Pathology and Laboratory Medicine Service, is directly responsible for ensuring that all laboratory testing performed within a VA facility, its outreach functions, and stand-alone outpatient clinics meet the quality improvement requirements listed as follows:

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

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

(c) There is an ongoing mechanism for monitoring and evaluating the usefulness and appropriateness of referral testing, i.e., that testing is sent to a CLIA '88-accredited laboratory, that the results obtained are of high quality, and that the test is appropriate for patient care.

(d) If tests are performed using different methodologies, instruments, or at other testing sites within the VA medical center, the Pathology and Laboratory Medicine Service must ensure that correlation studies between the main laboratory and these other test sites are performed at least twice yearly.

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

(f) All fatalities or other events considered “sentinel events” by The Joint Commission must be reported to the appropriate VA Pathology Regional Commissioner.

(2) **Privileged Provider Minimal Testing Standards.** The following minimal standards must be met for all testing, including waived and PPM procedures, regardless as to whether or not such testing is under the direct oversight of the Chief or Director, Pathology and Laboratory Medicine Service. While the Chief or Director, Pathology and Laboratory Medicine Service, in some instances may not be directly responsible for the laboratory results released by these providers, the Chief or Director, Pathology and Laboratory Medicine Service, must be involved in selecting test methods that are appropriate for use by the providers and must ensure that there is a mechanism in place that validates compliance with required testing standards, and VHA policy. The recommended mechanism to achieve this outcome is to include all such testing in the ancillary testing program.

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

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

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

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

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

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

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

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

(i) When testing is performed at more than one site within the organization, correlation testing must be performed between the testing sites at least twice per year. Correlation testing must be performed between the main laboratory and ancillary testing sites.

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

**d. Blood Bank Transfusion Service Requirements**

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

(2) All hemolytic and other life-threatening transfusion reactions must be immediately reported to the patient's physician.

(3) All hemolytic and other life-threatening transfusion reactions must be reported through the medical center's Patient Incident Reporting Program. All fatalities or other events considered "sentinel events" by The Joint Commission must be reported to the appropriate VA Pathology Regional Commissioner and the FDA. VA Pathology Regional Commissioners are then responsible for expeditiously reporting the incident to the Pathology and Laboratory Medicine Service National Enforcement Office.

(4) Biological product deviations must be reported directly to FDA and a copy forwarded to the appropriate Pathology Regional Commissioner.

**e. Anatomic Pathology Program Requirements.** Pathology and Laboratory Medicine Service must have an ongoing mechanism for monitoring and evaluating those aspects of care that are most important to the health and safety of the patient, including:

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

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

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

f. **External Proficiency Testing (PT) Program.** As an enhancement to the internal Quality Control Program, to ensure reliability of patient testing in the laboratory, and to maintain accreditation requirements, each Pathology and Laboratory Medicine Service and all Ancillary Testing Sites must subscribe to external PT programs that meet CLIA'88 requirements for all analytes for which PT is available, including waived testing, PPM, and unregulated analytes.

(1) The laboratory must participate in PT events that contain a minimum of five challenges per analyte per event, whenever five challenge events are available from the VA-contracted PT vendor.

(2) For analytes that do not have PT available, an alternative method must be in place to assess the method accuracy at least twice a year (e.g., split samples analyzed in conjunction with another laboratory, or testing materials with assigned values as unknowns). The laboratory must perform PT on every instrument (including backups) utilized for patient testing and for every site where patient testing is performed.

g. **Test Methods and Equipment Standards**

(1) Each Chief or Director, Pathology and Laboratory Medicine Service, must establish standards and policies for the selection of tests, validation and implementation of analytical systems, and test methods.

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

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

(b) If applicable, equivalent quality control is validated in accordance with current accepted scientific guidelines or accrediting agency requirements.

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

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

(5) The laboratory must, as a minimum, follow the manufacturer's recommendations for performing the testing including, but not limited to: quality control, reagent storage, maintenance, function checks, etc.

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

(7) Analytes measured from commercial test-kit procedures must be FDA-approved and meet the same general guidelines and standards of the analytical system.

(8) If tests are performed using different methodologies, instruments, or at other testing sites within the VA medical center, the Pathology and Laboratory Medicine Service must ensure that correlation studies between the main laboratory and these other test sites are performed at least twice yearly.

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

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

(9) Whenever possible, the major routine analytical systems must be interfaceable to the VA medical center's VistA computer system.

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

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

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

(b) All laboratory test results are carefully reviewed for accuracy of reporting by the testing personnel performing the test before the data is released to the health care providers and wards.

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

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

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

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

1. Previous patient test results display a delta check.

2. All significant abnormalities must be identified by an audible "beep" and a visual "flag" observed next to the test values.

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

(c) Ensure correct patient identification.

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

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

(4) The Necessary Reports Generated by VistA

1. In the case of the interim reports generated by VistA and intended to serve as the health care provider's work copy, the name of the requesting provider must be included along with the name and address of the testing facility.

2. The original report, or a duplicate of each report (including preliminary and final, except for microbiology preliminary report), must be retained in a manner that permits prompt retrieval of information by the testing site personnel and clinical personnel; it must be maintained as part of the patient's record.

i. **Specimen Identification for Drug Abuse Testing.** If specimens are collected for drug abuse testing, the Chief or Director, Pathology and Laboratory Medicine Service, must ensure a written specimen collection and identification policy, to be used in testing employees for drug

abuse, is in place. The laboratory must follow Federal regulations for collection and specimen management. This policy must include:

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

j. **Retention of Samples, Slides, and Records**

(1) Samples, slides, and records must be retained in accordance with the requirements of VHA Records Control Schedule 10-1, Section VIII- Laboratory Service (113), CLIA '88, AABB, CAP, The Joint Commission, or other deemed status accrediting organization, whichever is the most stringent.

(2) The test requisition or the test report must be maintained as part of the patient's chart or medical record complying with CLIA'88 requirement, if:

(a) The requisition is available to the laboratory at the time of testing and available to inspection groups upon request, and

(b) The test report is readily available to the laboratory and available to inspection groups upon request.

(3) PT records include those for:

(a) Test handling, preparation, processing, and examination;

(b) The results of reporting;

(c) The signed attestation statement; and

(d) The evaluation reports.

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

## 8. ANCILLARY TESTING

### a. Scope

(1) This paragraph provides direction and guidance to VA medical facilities regarding ancillary testing. Ancillary testing is defined as laboratory testing or services performed within a VA medical center or its outreach functions (clinic, et al.), but outside the physical facilities of the main clinical laboratory. This includes testing performed by a VA employee or a contracted service employee in a patient's home under the HBHC Program or testing done as Point of Care at bedside. **NOTE:** *Providers and other non-laboratory personnel perform these tests.*

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

1. Waived, PPM and non-waived testing performed outside of the physical limits of the main VA Pathology and Laboratory Medicine Service.

2. Testing performed by non-laboratory personnel, including privileged providers.

(b) Ancillary Testing encompasses:

1. POCT;

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

3. Testing that is under the umbrella of the main laboratory; and

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

(2) All ancillary testing sites are required to be under either the quality oversight or technical direction of the Chief or Director, Pathology and Laboratory Medicine Service, and inspected and fully accredited by an appropriate, nationally recognized CMS "deemed" accrediting body.

(a) An Ancillary Testing Coordinator generally monitors and oversees the ancillary testing sites for the Chief or Director, Pathology and Laboratory Medicine Service.

(b) For sites that are not under the direct oversight of the Chief or Director, Pathology and Laboratory Medicine Service, such as might be found at some facilities with PPM testing, the Chief or Director, Pathology and Laboratory Medicine Service, remains responsible for ensuring that the testing is carried out in accordance with 42 CFR 493 and VHA policy.

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

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

(3) Copies of quality management records for all VA Ancillary Testing Sites must be maintained within the main clinical laboratory.

b. **Responsibilities**

(1) The Chief of Staff or Director of Clinical Services provides the Chief or Director, Pathology and Laboratory Medicine Service, with the location and type of all ancillary testing equipment, including bedside testing sites, methodology to be used, and the estimated number of tests to be performed annually. *NOTE: The list must be updated each time new methods and/or instruments are added or deleted.*

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

c. **Ancillary Testing Coordinator.** The Ancillary Testing Coordinator, or the individual responsible for the laboratory portion of the ancillary testing program, must be a fully qualified medical technologist with at least 4 years of experience in appropriate areas of laboratory testing. This individual:

(1) Provides technical oversight for all Ancillary Testing Sites.

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

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

(4) Participates in the planning, design, implementation, and assessment for all elements of the Ancillary Testing Quality Management Program.

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

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

d. **Test Results.** The results of all ancillary testing must be entered into the official VA computer package. *NOTE: Privileged providers performing waived or PPM testing as a part of their routine exam, may enter testing results in the progress notes. The VA minimal testing requirements for documentation must be met (see subpar. 7c(2)).*

e. **Ancillary Testing Devices**

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

(2) Routine maintenance and cleaning must be performed as specified by the manufacturer.

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

e. **Patient Self-testing.** When patients are in a VA inpatient or ambulatory care setting, they may not perform self-testing except when self-testing is required as part of a patient education program or the patient is in a domiciliary or similar situation and adjusting their own medication. Results from patient self-testing may not be utilized by VA providers for patient diagnosis or treatment. Laboratory personnel must be available to participate in patient education on the maintenance and cleaning of self-testing devices.

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

## **9. IMMUNOHEMATOLOGY, BLOOD TRANSFUSIONS, AND TRANSFUSION MEDICINE TESTING**

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

(1) Only blood from volunteer donors can be utilized. In emergent situations, pheresis platelets and white blood cells (WBC) from paid donors may be utilized, if components from volunteer donors cannot be obtained.

(2) A means must be provided for patients to undergo autologous pre-operative donation, whether at the medical center or at a blood center supplying other blood components to the medical center. The patient's provider is responsible for ensuring patient safety and advising against autologous donation if physical risks to the patient are evident.

(3) Although VA policy discourages designating specific units of blood or components for transfusions for a specific patient (directed donations), VA must ensure a means to provide such units.

(4) Transfusion practices and problems must be reviewed regularly and documented in the minutes of the multidisciplinary committee of the medical center responsible for oversight of the blood bank or transfusion service.

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

(6) VA Standard Form (SF) 518, Blood or Blood Component Transfusion, or its authorized equivalent, must be used to order all blood and blood components and for the documentation of the transfusion. *NOTE: This also applies to contracted blood bank services.*

**b. Inspection, Accreditation, and Standards**

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

*NOTE: Reference for this action is FDA-Compliance Program Guidance Manual – October 1, 2006 Chapter 42 – Blood and Blood Products Inspection of Licensed and Unlicensed Blood Banks, Brokers, Reference Laboratories, and Contractors – 7342.001 Appendix J.*

*NOTE: Noncompliance issues cited on FDA inspection must be addressed and corrected.*

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

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

c. **Responsibilities.** Each VA medical facility Director is responsible for appointing a Transfusion Officer who must be a physician with knowledge and experience in blood banking or hematology. The Transfusion Officer is responsible for oversight of the blood usage review.

**d. Operation of a Homologous (Allogeneic) and Autologous Blood Donor Programs**

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

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

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

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

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

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

(5) Testing for markers of transfusion transmitted disease can be performed at another VA medical center or at an outside laboratory, providing that laboratory holds a current certification of accreditation under CLIA '88.

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

e. **Special Procedures**

(1) **Directed Blood Donations**

(a) Directed donations are provided by friends, or family of patients, and earmarked exclusively for a specific patient. Although VA policy discourages directed donations, there may be instances where the patient stipulates that directed blood be used to meet transfusion needs.

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

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

(2) **Therapeutic Phlebotomy**

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

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

**(3) Therapeutic Apheresis**

- (a) Facilities that perform therapeutic apheresis must have the medical and technical expertise to perform this procedure.
- (b) Therapeutic apheresis procedures may be performed only when ordered by the physician.
- (c) A unique informed consent is required for apheresis procedures; the patient must be apprised of all relevant aspects of the procedure in advance.
- (d) A physician must be on the premises and immediately accessible to handle adverse reactions to apheresis.
- (e) When therapeutic apheresis procedures are conducted within the medical center but not under the auspices of the laboratory or by contracted services, the Transfusion Medicine Director must provide guidance to the service performing the procedure to ensure the procedures are performed consistent with AABB standards.

**(4) Perioperative Autologous Procedures**

- (a) For laboratories that have assumed responsibility of the perioperative autologous or blood salvage procedures performed during surgery, the program must comply with AABB Standards.
- (b) When perioperative autologous procedures are conducted within the medical center but not under the auspices of the laboratory or by contracted services, the Transfusion Officer must provide guidance and review of the standard operating procedures.

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

- (a) For laboratories that have accepted responsibility for the acquisition and storage of HCT/Ps, the products must be acquired from manufacturers that are accredited and registered with the FDA.
- (b) Blood banks must establish mechanisms to capture traceability of the product from acquisition, to storage, distribution, and final disposition. Standard operating policies and procedures must adhere to the facility accrediting agency requirements.

**f. Transfusion Complications****(1) General Principles**

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

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

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

(d) All necessary remedial actions taken to prevent recurrences of transfusion reactions must be documented in the patient's chart, in the VA medical center blood bank, and in the minutes of the VA medical center multidisciplinary committee responsible for oversight of the blood bank or transfusion service.

## **(2) Transfusion Transmitted Diseases**

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

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

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

## **g. Computer Requirements for Blood or Blood Component Transfusion**

### **(1) Responsibilities**

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

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

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

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

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

(d) The Chief or Director, Pathology and Laboratory Medicine Service, or designee, in conjunction with the Transfusion Officer, is responsible for:

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

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

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

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

## **(2) Minimum Standard Operating Procedures (SOP) for the Computer Functions**

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

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

(c) Written procedures must exist that:

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

a. Identify who corrected the data,

b. Control access of who can correct data, and

c. Monitor the number of changes for both reportable and non-reportable data. *NOTE: If it is a reportable result, the results must be identified as "corrected."*

2. Describe methods for maintaining data integrity, including:

a. An audit trail for changes in verified data,

b. Periodic checks on data integrity following both scheduled and unscheduled downtimes, and

c. The mechanism for reconstructing lost data.

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

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

a. View data,

b. Enter data,

c. Edit data, and

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

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

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

(3) **Validation Testing.** Prior to the release of laboratory software, VBECS developers are required to subject the software to intensive testing and review as part of the development and verification process. A great deal of the functionality of software is affected by the operating

system, interaction with other software packages in the same database, and files which accommodate local modification. This “verification” is not equivalent to “validation testing,” nor can it be substituted for mandatory “validation testing.” *NOTE: Additional details and a sample plan are included in the Blood Bank User Manual Appendix provided with the VA VBECS software.*

(a) In order to confirm that the computer software logic functions as desired, using the local database, operating system, and hardware configuration, validation testing must be performed in accordance with the current requirements of the various accrediting and regulatory agencies. Computer systems used in blood establishments must be validated in accordance with current regulatory requirements and standards for equipment, such as the FDA (see 21 CFR 211 and 21 CFR 606), AABB standards, and CLIA '88 (42 CFR 493).

1. A Validation Test Plan must exist which details the individual responsible for:
  - a. Developing, executing, and reviewing results of test cases;
  - b. Evaluating the validation process;
  - c. Determining the acceptance criteria; and
  - d. Determining acceptability of testing.
2. The Validation Test Plan must address a variety of issues, including:
  - a. The physical description of the computer hardware;
  - b. The manufacturer and model;
  - c. The number and location of terminals;
  - d. The list of modems and authorized access to modems;
  - e. The identity of any instrument interfaces;
  - f. The internal interface (module to module) and external interfaces (peripheral, other application software, and network communications, etc.);
  - g. The environmental conditions;
  - h. The operating system and version;
  - i. The application software and version;
  - j. A listing of options and programs to which blood bank personnel have access;

k. A summary of the implementation process, including action to be taken if deviations from expected performance occur; and

1. The full variety of test cases. **NOTE:** *These test cases must ensure that all safety critical intended use functions have been included.*

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

a. Definitions for successful completion of the test cases, as well as for when the user requirements will be met; and

b. The process for evaluation of unaccepted occurrences to determine whether the occurrence is critical or non-critical.

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

1. A control function is a system function that causes an activity to occur, or that influences the behavior of the user of the system. Control functions may exist even when competent human intervention occurs. Examples include functions in which: labels are created; records are created, modified, retrieved, deleted and/or archived; data is compared to a standard; or a warning message is generated.

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

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

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

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

a. Data entry methods,

b. Information security procedures,

c. Program overrides,

d. Data storage, and

- e. Retrieval and traceability of results.
- 4. A variety of test conditions must be addressed, including:
  - a. Normal data;
  - b. Exceptional data which provides an unusual twist for the program to force the program to react to data, or a situation that might be unexpected;
  - c. Boundary situations to force the evaluation of conditions that are of borderline validity;
  - d. Invalid data to force a program to prove that it can detect invalid input; and
  - e. Stress conditions, to determine whether the system has acceptable performance limits.
- (c) Validation testing must be performed in an environment which must be a duplicate of the operating system file structure, programs, and site specific options, etc., of those found in production. Validation testing must be performed in a robust test account that is a fully patched mirror version of the production account.
- (d) Validation testing must be performed in accordance with the specified time frames, as well as the requirements outlined by VA and various regulatory agencies:
  - 1. Retrospective validation is required for current systems and/or software in operation before the FDA memorandum of September 1989. This validation testing must include the full scope of testing detailed in subparagraph 9g(3)(b).
  - 2. Prospective validation testing must be performed before software is put into use for daily operations. This testing must be completed before parallel, manual systems are discontinued.
  - 3. Prospective change control validation testing must be performed before revisions, or modifications, in software are in use for daily operations. This validation testing may encompass a more limited scope depending on the nature of the change and the interaction of the specific routine on other functions. Hazard analysis needs to be performed when changes occur in order to determine the scope of validation. This analysis is done to identify the critical processes, operating, and performance parameters affected by the change and, hence, that require validation.
- (e) Validation testing must be documented in a comprehensive manner.
  - 1. Testing documentation must include observations from testing. This may be in the form of:
    - a. Work sheets,
    - b. Screen prints,

- c. Logging files,
- d. Printed reports,
- e. Written transcriptions,
- f. Data tapes, or
- g. Data disks.

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

#### (4) Tracking of Errors

(a) A record, or log, must exist to detail:

1. Unusual occurrences and errors ("bugs"). All safety critical anomalies (bugs) or anything observed in the documentation or operation of the computer or software that deviates from expectations based on performance, or reference documents, need to be identified. Documentation must include a description of the correction action and the summary of results.

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

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

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

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

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

**(5) Training of Personnel**

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

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

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

**(6) Documentation**

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

(b) In accordance with the provisions of subparagraphs 9g(3)(e) and 9g(4), there must be documentation of validation testing and of the errors which occur either during validation testing, or after implementation.

(c) Documentation of training must be maintained.

**h. Blood Bank or Transfusion Service Quality Plan**

(1) Each blood bank or transfusion service must develop and maintain a quality plan that meets the requirements of regulatory or accreditation agencies.

(2) The quality plan must address each of the following:

(a) Organization;

(b) Resources;

(c) Equipment;

(d) Supplier and customer issues;

(e) Process control;

(f) Documents and records;

(g) Deviations, non-conformances, and Adverse Events;

(h) Internal and External Assessments;

- (i) Process improvement through corrective and preventive action; and
- (h) Policies regarding facility issues (space, environment, etc.) and safety.

*NOTE: An example of a written policy plan (Quality Plan) approved by AABB may be found in Appendix A.*

## **10. SURGICAL PATHOLOGY, CYTOPATHOLOGY AND ELECTRON MICROSCOPY TESTING**

### **a. Scope**

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

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

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

(c) Standards for anatomic pathology in VA must be in accordance with those published in the current edition of The Joint Commission Comprehensive Accreditation Manual for Laboratory and Point-of-Care Testing, and those of the CAP Commission on Laboratory Accreditation.

(d) Current accreditation by appropriate, nationally-recognized, CMS “deemed” accrediting bodies is required for all VA medical facilities providing anatomic pathology services.

(e) Only qualified, licensed, and locally privileged pathologists certified by the American Board of Pathology in Anatomic Pathology can provide the written report for all surgical pathology, autopsy, diagnostic electron microscopy, and abnormal cytopathology examinations.

(f) VHA Central Office Pathology and Laboratory Medicine Service arranges for programs for ongoing quality improvement, and as appropriate, PT in surgical pathology and cytopathology in each VA medical facility that performs these services.

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

(a) VA pathologists must review and issue a report on the slides of all specimens obtained outside VA that are used as a basis for treatment or surgery.

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

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

(a) All cytology specimens obtained at VA medical facilities must be sent to Pathology and Laboratory Medicine Service for evaluation and diagnosis.

(b) All screening of VA cytopathology slides must physically be performed in the laboratory of the medical facility providing the review.

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

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

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

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

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

2. The Chief or Director, Pathology and Laboratory Medicine Service, has certified the competency of the cytotechnologist to report negative GYN cytopathology specimens by written delegation; and

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

4. The cases subjected for rescreening must include some cases from high-risk patients, as well as random negative cases, based upon criteria established by the Chief or Director, Pathology and Laboratory Medicine Service.

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

recognized, CMS “deemed” accrediting body. VHA facilities that obtain these services (contract or sharing) from a non-VHA organization must ensure that the organization providing such services has a current, valid CLIA ’88 number and that these specific frozen section services are covered by that CLIA ’88 number.

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

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

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

(5) **Electron Microscopy.** Diagnostic electron microscopy services must be provided regionally at VA facilities (see subpar. 10j).

**b. Responsibilities of the Chief or Director, Pathology and Laboratory Medicine Service.** The Chief or Director, Pathology and Laboratory Medicine Service, is responsible for;

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

(2) Ensuring individual performance appraisals are performed for all staff; and

(3) Actively participating in the appraisal process.

**c. Evaluation of Anatomic Pathology Specimens**

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

(2) All anatomic pathology reports must be documented in the VA medical facility's VistA. This includes those reports on VA patient specimens evaluated through contract, fee basis, sharing agreements, or at other VA medical facilities.

(3) If VA anatomic pathology specimens are evaluated at a non-VA facility, that laboratory must be currently accredited by an appropriate, nationally-recognized CMS “deemed” accrediting body and have a Certificate of Accreditation issued by HHS under the provisions of CLIA ’88.

(a) Reports of such evaluations must be transcribed onto SF 515, Tissue Examination, and authenticated by the Chief or Director, Pathology and Laboratory Medicine Service, or a VA staff pathologist.

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

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

(d) All contract pathologists must meet the qualifications found in Paragraph 12, and are governed by all provisions of Paragraphs 4, 6, and 8.

**d. Continuous Quality Improvement (CQI)**

(1) Quality improvement in anatomic pathology, including surgical pathology, cytopathology, diagnostic electron microscopy, and autopsy pathology, focuses on mechanisms to maintain and improve the quality of care for VA patients. Emphasis needs to be given to those factors shown to generate the greatest potential of risk to the patient and those most important to patient care.

(2) To be included in each local VA medical facility's Quality Improvement (QI) Plan are mandatory external QI, and as appropriate, PT Programs in anatomic pathology. These programs are arranged and monitored by the National Director, Pathology and Laboratory Medicine Service, and include, but are not limited to, the following:

(a) An anatomic quality improvement program (e.g., The Armed Forces Institute of Pathology Histopathology Quality Assessment Program);

(b) An external surgical pathology review program ( e.g., the Armed Forces Institute of Pathology Systematic External Review of Surgicals (SERS));

(c) A non-GYN cytopathology Program, (e.g., The American Society of Clinical Pathologists (ASCP) non-GYN assessment program); and

(d) A CMS-approved GYN cytopathology proficiency testing program (e.g., the ASCP GYN PT program, etc.); and

(e) Additional similar programs, which may be included at the discretion of each local Chief or Director, Pathology and Laboratory Medicine Service.

**e. Competency Assessment in Anatomic Pathology (using QI and PT programs)**

(1) QI and PT programs are intended to identify laboratories and individuals who are unable to reliably distinguish clinically important findings and report them in a conventional manner to communicate the important finding(s) to the patient's provider.

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

(a) These programs must:

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

a. Having identified deficiencies, testing leads to focused reviews and additional education and training as required to remedy the deficiency.

b. The intent is to continually improve the anatomic pathology services provided.

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

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

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

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

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

(b) Testing material must:

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

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

(c) Pathology and Laboratory Medicine Service in VHA Central Office is responsible for:

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

2. Providing proficiency review of the Diagnostic Electron Microscopy Programs in Pathology and Laboratory Medicine Service, when indicated.

3. Administering the QI and PT programs. Reports of medical facility and individual performance must be submitted annually to the Chief or Director, Pathology and Laboratory Medicine Service, at each VA medical facility providing anatomic pathology service.

4. Overseeing the activities of each VA medical facility's anatomic pathology service.

*NOTE: If indicated, focused reviews are to be conducted and corrective action implemented to ensure that each Pathology and Laboratory Medicine Service continues to provide high standards of service and patient care.*

(3) The Chief or Director, Pathology and Laboratory Medicine Service, is responsible for recognizing the need for additional education or training, based on the reports of performance and the results of the CQI program.

f. **Accessioning and Examination of Specimens**

(1) All specimens removed during surgical procedures must be sent to Pathology and Laboratory Medicine Service for evaluation by a qualified pathologist unless specifically exempted by the governing body of the facility.

(a) Cytology specimens obtained at the VA medical facility (both outpatient and inpatient) must be sent to the Pathology and Laboratory Medicine Service for accessioning.

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

(c) All tissue and cytology specimens sent to Pathology and Laboratory Medicine Service must be accompanied by an appropriately completed SF 515.

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

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

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

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

(b) Additional documentation by electronic communication (e.g., view alerts, local Vista, e-mail, etc.) is suggested.

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

(5) All cases with unexpected diagnoses of clinical significance, and diagnoses of malignancy not previously established (excluding skin squamous and basal cell carcinomas), must be reviewed by a second pathologist prior to issuance of the final report. Preliminary reports may be issued while the review by a second pathologist is being obtained.

g. **Internal Quality Control - Mandated Second Review of Cases.** The Chief or Director, Pathology and Laboratory Medicine Service, must ensure that a diagnostic review of surgical, fine needle aspirates, and cytology diagnosis, is performed by a second pathologist on a quarterly basis for at least 10 percent of all surgical pathology cases, fine needle aspirates, and cytology cases diagnosed in that medical facility.

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

(2) In VA medical facilities with two or more pathologists, reviews need to be arranged within the staff and the surgical pathology report needs to document the concurrence with the diagnosis. In cases where there is disagreement, a third opinion needs to be obtained expeditiously, either from local consultants, such as pathologists at an affiliated medical school, or from Armed Forces Institute of Pathology, with a request for consultation. If there is a significant change in diagnosis that affects the patient's treatment, the Chief or Director Pathology and Laboratory Medicine Service, advises the Chief of Staff or Director of Clinical Services, and the patient's physician, or an appropriate clinical staff provider, who must take action to contact the patient and revise or amend the treatment. The reviewing pathologist’s name must be included in the final report.

(3) In VA medical facilities with only one pathologist, a documented, signed second opinion must be obtained on at least 10 percent of all surgical, fine needle aspirations, and cytology cases. In cases where long distances between medical facilities, inclement weather, or logistical problems preclude review within 48 to 72 hours, the second review must be performed as soon as possible, preferably no more than 7 to 10 days from the first diagnosis. The second opinion must be obtained through one or a combination of the following:

(a) Local consultants, or

(b) Another VA medical facility with two or more pathologists on its staff, or

(c) The Armed Forces Institute of Pathology through the VA-Armed Forces Institute of Pathology memorandum of agreement.

(4) In VA medical facilities with no permanent pathologist, the Chief of Staff ensures that the second review of all surgical pathology and cytology diagnoses is provided by a qualified

pathologist (board certified, licensed, and experienced in surgical pathology work). The 10 percent review system is also mandated for contract, fee-basis, or sharing agreement pathologists who provide surgical pathology, or cytology diagnostic services for VA medical facilities.

*NOTE: Electronic or paper dated log books and documentation of second reviews are to be maintained in the VA medical facility's Pathology and Laboratory Medicine Service. The log books must contain or document provider specific information.*

(5) In no case will a resident physician act as a second reviewer for a staff pathologist. Similarly, a review of a resident physician's diagnosis by a staff pathologist does not constitute a second review in this context. All pathology and cytology cases reviewed and signed by a board-eligible pathologist must be countersigned by a board certified pathologist.

#### h. Anatomic Pathology Reporting and Specimen Slide Storage

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

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

- (a) Full patient identification.
- (b) Identity of the patient's provider.
- (c) Identity of the submitting provider.
- (d) Date and nature of the procedure used to obtain the specimen.
- (e) Type and location (organ) of the specimen.
- (f) Pertinent clinical information and other information contained on the requisition.
- (g) Identity (name and address) of the VA medical facility where the specimen was processed.
- (h) Unique accession number of the specimen.
- (i) Date and text of the pathological evaluation.
- (j) Name and authentication of the responsible pathologist.

(k) All special procedures performed and consultations obtained.

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

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

(4) **Copies.** Only authenticated copies of diagnostic anatomic pathology reports with the patient's name, Social Security Number (SSN), name and address of the VA medical facility, and the name of the staff pathologist can be produced and circulated outside of Pathology and Laboratory Medicine Service. Whether Pathology and Laboratory Medicine Service or the medical records department of the medical center releases copies of reports is determined by local policy.

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

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

(7) **Indexing.** The diagnoses for all anatomic specimens must be indexed by patient for ease of retrieval.

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

(9) **Surgical Pathology Report.** The final Surgical Pathology Report must, in addition to the items in subparagraph 10h(2), include:

(a) A description of the specimen received;

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

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

(10) **Modification and Supplemental Additions to Released Reports**

(a) Once released to the medical record, any modification or supplemental addition to the final anatomic pathology report must be clearly indicated, as well as the person responsible for

the modification, and the date of the modification. The original information must also be retrievable.

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

(11) **Retention and Disposal.** Retention and disposal of Pathology and Laboratory Medicine Service's copies of anatomic pathology reports are to be in accordance with all applicable Federal standards (i.e., the VA Record Control System (RCS) 10-1). The RCS 10-1 is the definitive guide for retention of reports and other materials, but the accreditation standards, as well as the following guidelines generally apply.

(a) The copies must be retained for 25 years.

(b) When they no longer serve a useful purpose, wet stock of surgical specimens, and submitted cytology material, must be disposed of under the responsibility of the Chief or Director, Pathology and Laboratory Medicine Service.

(c) Representative glass slides and electron microscopic materials on suspicious or positive cases must be retained for at least 25 years.

(d) Representative paraffin and plastic blocks on negative cases must be retained for at least 10 years.

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

j. **Diagnostic Electron Microscopy (EM) in Laboratory Services**

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

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

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

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

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

(2) Functions of a diagnostic EM Program in the VHA Laboratory Service include:

- (a) Enhancement of morphologic diagnosis.
- (b) Provision of diagnostic EM services at the parent hospital and to other VA facilities in the geographic area.
- (c) Provision of training in EM for professional and technical personnel.
- (d) Inclusion, where appropriate, of the EM findings in facility teaching and conferences.
- (e) Development, where indicated, of sharing agreements to provide EM services for non-VA medical institutions.

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

(a) VA medical facilities wishing to establish a diagnostic EM Program in Pathology and Laboratory Medicine Service must prepare an application in accordance with the current requirements (which may be obtained from the National Electron Microscopy Program Coordinator (113), VA Medical Center, Durham, NC 27705).

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

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

(d) The application must be reviewed by the Ad Hoc EM Review Group on the merit of the proposal, and a recommendation made to the National Director, Pathology and Laboratory Medicine Service (115A). **NOTE:** *A site visit may be included in the analysis of the proposal by members of the review group.*

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

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

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

(b) Recurring support requires funds for personnel, supplies, and a service contract. The cost of the service contract is normally prorated among users other than Pathology and

Laboratory Medicine Service, for example, as Research and Development working with Education Service through a Structured Joint Utilization Agreement.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

k. **Operations of Diagnostic EM Units.** An approved operational EM Unit is considered a permanent addition to the VA medical facility's Pathology and Laboratory Medicine Service provided the utilization or productivity and quality of EM services remain satisfactory, as judged by the VA National Electron Microscopy Coordinator.

(1) **Records and Reports**

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

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

2. The report must include:

- a. Dates of accession and diagnosis;
- b. A description of the light and electron microscopic findings;
- c. A specific diagnosis; and
- d. Where appropriate, the pertinent literature reference.

3. The report must be signed by the pathologist making the diagnosis. **NOTE:** *Electron micrograph prints or digital images need not be distributed or included routinely with the reports.*

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

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

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

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

(c) **Records Retention.** Samples, slides, and records must be retained in accordance with the requirements of VHA Records Control Schedule 10-1, Section VIII- Laboratory Service (113),

CLIA '88, AABB, CAP, and The Joint Commission or other deemed status accrediting organization, whichever is the most stringent. For EM materials, these guidelines are specified as follows:

- |   |  |
|---|--|
| <u>1.</u> Wet tissue                            | Must be retained 2 weeks after final report.       |
| <u>2.</u> Plastic Blocks                        | Must be retained 10 years from date of exam.       |
| <u>3.</u> Semi-thin section                     | Must be retained 1 year from date of exam.         |
| <u>4.</u> EM Grids                              | Must be retained 1 year from date of exam.         |
| <u>5.</u> Reports                               | Must be retained 25 years after final report.      |
| <u>6.</u> Accession log                         | Must be retained 5 years after specimen receipt.   |
| <u>7.</u> Maintenance records                   | Must be retained 2 calendar years.                 |
| <u>8.</u> Negatives or digital images           | Must be retained 25 years after final report.      |
| <u>9.</u> Prints which are a part of the report | Must be retained 25 years (along with the report). |
| <u>10.</u> Remaining prints                     | Must be retained 1 year after final report.        |

(d) Numerical (productivity) data from the EM program are reported monthly in LMIP by using the VistA workload reporting module for Pathology and Laboratory Medicine Service.

(e) Annual reports are required from each EM Unit in Pathology and Laboratory Medicine Service.

1. The reports are prepared by the program Chief or Director, EM Unit, and transmitted through the Chief or Director, Pathology and Laboratory Medicine Service, and the medical facility Director, to the National Electron Microscopy Program Coordinator.

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

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

**(2) Monitoring**

(a) Appropriate monitoring procedures for emission of radiation from each electron microscope must be established in keeping with the existing VA safety policy (see VHA Handbook 7701.1).

(b) The following procedures must be used in monitoring:

1. Analysis of the numerical data in the workload section of the VistA Laboratory Module.
2. Analysis of the annual report.
3. Quality assessment by the Ad Hoc EM Review Group, annually and on an as needed basis.

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

(a) Such arrangements, which include appropriate pro-rating of recurring costs, are to be developed locally, and specified in written Joint Utilization Agreements or under the Enhanced Health Care Resources Sharing Authority contained in the Veterans Health Care Eligibility Act of 1996 (Public Law 104-262), ensuring that first priority is given to critical diagnostic needs of VA patients.

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

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

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

(c) The contents of the agreements need to be concurred in, and the document signed by the:

1. Chief or Director, Pathology and Laboratory Medicine Service;
2. The individual responsible for research and development at the facility;
3. The individual responsible for education at the facility; and
4. Chief of Staff, Director of Clinical Services, or Director of Medical Staff.

(d) Completed agreements must be forwarded to the medical center Director for review and approval.

1. If no changes are indicated, the medical facility Director is to notify the local concerned personnel that the agreement remains in effect.

2. If need for substantive changes is identified, a new agreement must be prepared and forwarded to the medical center Director.

#### (4) **Quality Assessment**

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

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

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

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

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

1. The quality of the electron micrographs;

2. The description of the findings in the report;

3. The accuracy of the diagnosis, and the clinical significance of the ultrastructural findings; and

4. The citation of literature references, when appropriate.

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

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

1. Annually, the National Director, Pathology and Laboratory Medicine Service (115A), prepares letters containing an evaluation of each diagnostic EM Program and concluding with the assigned rating. These letters are sent to the VISN Director.

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

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

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

*NOTE: The VISN or medical facility Director, during the grace period, may decide after consultation with the medical staff Director, the Chief or Director, Pathology and Laboratory Medicine Service, and the program Chief or Director of the EM Units, that patient care needs could be met as well by closing the EM Unit and obtaining the services from another VA or non-VA facility. In such instances, the medical facility Director must discuss the local decision with the National Director, Pathology and Laboratory Medicine Service (115A), before any final action for closure is taken.*

#### **(5) VHA Central Office EM Program Responsibilities**

(a) Pathology and Laboratory Medicine Service, VHA Central Office, has the responsibility for fulfilling the following functions:

1. Collection and analysis of utilization data from all electron microscopes assigned to Pathology and Laboratory Medicine Service.

2. Promotion of maximal joint utilization of electron microscopes for diagnostic purposes, and advice on Structured Joint Utilization Agreements.

3. Recommendations on relocation of under-utilized electron microscopes.

4. Recommendations to VISNs on the need for additional, or replacement, electron microscopes.

5. Maintenance of a current inventory of all electron microscopes assigned to Pathology and Laboratory Medicine Service.

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

1. The group is chaired by VA's EM Coordinator and serves in an expert advisory capacity to the National Director, Pathology and Laboratory Medicine Service (115A).

2. The group's primary functions are to:

a. Assess the quality of diagnostic EM;

b. Review applications for new diagnostic EM Units, and make recommendations to the National Director, Pathology and Laboratory Medicine Service (115A); and

c. In special situations, review selected annual reports and participate in site visits to EM Units.

(c) If they offer special expertise, equipment, or procedures to other VA medical centers and their sharing agreement partners, the Director, Pathology and Laboratory Medicine Service (115A), may designate particular diagnostic EM programs as benchmark Centers of Excellence.

1. The primary goal of a Center of Excellence is to serve as a benchmark for other EM facilities and to facilitate the sharing of the capabilities available in these special laboratories with other VA medical centers.

2. The National EM Coordinator acts as the principal expert in determining which centers are chosen.

### 1. **Immunohistochemistry**

(1) In some laboratories immunohistochemistry functions are an important adjunct to the conventional techniques used in anatomic pathology. While immunocytochemical procedures are more complex and difficult to perform properly than many "special stains," immunocytochemical results must, like other histochemical procedures, be interpreted in the context of all of the available information (e.g., clinical history, gross findings, light microscopy, EM, etc.), and do not stand alone.

(2) Accordingly, the policies and procedures outlined for continuing quality assessment and improvement also apply to immunohistochemical procedures.

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

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

m. **Discontinuation or Merger of Anatomical Pathology Services.** When anatomical pathology services at a VA facility are discontinued or merged with another VA facility, all

documentation and specimens, which are required to be maintained (see par. 9) must be transferred to the VA facility where the scope of services for the patients of that facility has been transferred.

## 11. POST-MORTEM EXAMINATIONS

a. **Scope.** All VA medical centers must provide post-mortem examination services (either on-site, through contract, or sharing agreement). If these services are not available at a particular VA medical facility, arrangements must be made for the autopsies to be performed at another VA or other non-VA facility. The availability of these services must be made known to the family of each decedent. The medical staff is to attempt to secure authorization for post-mortem examination in all deaths.

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

(a) Arrangements for securing post-mortem examination authorizations;

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

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

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

(2) Findings on all post-mortem examinations need to be presented to the medical staff on a regular basis, as expeditiously as possible. Such reviews need to occur with the frequency appropriate to the level of activity in the medical center, but at least once each quarter.

(3) The Chief or Director, Pathology and Laboratory Medicine Service, is responsible for the direction of professional aspects of post-mortem examination, including:

(a) The custody of bodies co-signed to the post-mortem examination suite;

(b) Performance of the post-mortem examination and the diagnoses;

(c) Preparation of protocols and reports (provisional and final);

(d) Retention and disposition of post-mortem examination tissue (blocks, microscopic slides); and

(e) Professional support of clinical and administrative activities related to the post-mortem examination.

(4) In all instances there must be a legal authorization for post-mortem examination signed by the appropriate next-of-kin before beginning a post-mortem examination, except as provided in Title 38 CFR 17.170.

(a) Whenever possible, the health care provider responsible for the care of the patient at the time of death is the designated person to request permission from the next-of-kin to perform a post-mortem examination.

(b) The original copy of the authorization, SF 523, Authorization for Autopsy, or transcript of recorded telephone conversation, must be included in the deceased's medical record.

(5) Post-mortem examination may be performed for medical-legal reasons in cases of unexpected death upon compliance with 38 CFR 17.170

b. **Post-Mortem Examination Rates as a Percentage of Hospital Deaths.** VA policy for post-mortem examination rates encourages the maximum number of post-mortem examinations on patients within a wide range of clinical categories, rather than to seek an arbitrary fixed post-mortem examination rate as a percentage of all hospital deaths. Particular emphasis needs to be exerted to obtain permission for the autopsy of unexpected deaths and deaths proximate to interventional procedures (refer to current VHA policy).

(1) **Deaths with Medical-legal Significance.** Certain deaths that occur in a VA medical center are of potential medical-legal significance. These deaths may be called Medical Examiner, or Coroner's cases, in that they must be reported to a local investigating agency and/or the United States Attorney through the Regional Counsel, in accordance with requirements of 38 CFR Section 17.170(c)(d), and 38 U.S.C. Sections 5701(f)(2) and 7332. In such deaths, the Medical Examiner or Coroner may assume jurisdiction and is responsible for the performance of the autopsy. In such deaths, the autopsy may be performed by VA staff, but only with the approval of the Medical Examiner or Coroner and with the written consent of the next-of-kin.

(a) If the report of a death is made to the local investigating agency of jurisdiction and they decline jurisdiction, and if the United States Attorney has been informed of the death, then a post-mortem examination may be performed on the remains providing written consent is obtained from the next of kin.

(b) Under certain circumstances, detailed in 38 CFR 17.170, the Chief of Staff or medical center Director may cause an autopsy to be performed in the absence of consent from the decedent's next of kin.

(2) **Deaths for which the Armed Forces Institute of Pathology has established Special Registries.** Certain groups of veterans may yield valuable findings at post-mortem examination. These groups include veterans who:

(a) Served in Desert Storm, Persian Gulf, or Kuwait.

(b) Were exposed to radiation during the atom bomb detonations in the United States, Hiroshima, Nagasaki, and other sites.

(c) Are known to have been Prisoners of War (POWs). **NOTE:** *For post-mortem examinations performed on former POWs, the guidelines provided in Appendix C are to be followed.*

(d) Were exposed to Agent Orange during the Vietnam war.

(3) In addition to the customary local examination and reporting of pathologic material, a duplicate set of slides, blocks and representative wet tissue need to be forwarded to the Armed Forces Institute of Pathology for each of the preceding groups of veterans.

(4) All material shipped to Armed Forces Institute of Pathology must be packed according to applicable regulations and addressed to: Director, Armed Forces Institute of Pathology, "Attention Gulf War, Radiation, or POW (choose appropriate designation) Registry."

**c. Performance of Post-mortem Examinations**

(1) A complete clinical record and a listing of clinical questions, or concerns related to possible post-mortem examination findings, must be furnished to the pathologist by the clinical attending physician prior to beginning the post-mortem examination.

(2) The gross post-mortem examination must be performed under the supervision of a qualified, licensed, credentialed physician, normally a pathologist qualified in anatomic pathology.

(a) Some of the activities may be delegated to suitably trained allied health personnel; however, only under the direct, personal supervision of a qualified pathologist.

(b) Members of the house staff who perform post-mortem examinations must be under the supervision of a pathologist.

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

(4) There will be strict adherence to the family's wishes as recorded on the SF 523.

(5) Care must be exercised that there is no undue delay in performing the post-mortem examination which would inconvenience the family of the decedent.

(6) As soon as possible, the pathologist is to notify the attending physician as to the time of post-mortem examination, and arrange for a demonstration the gross findings.

(7) Do not embalm before conducting a post-mortem examination. Embalming prior to post-mortem examination, whether by arterial injection or by intracavitary trocar injection, is not to be done because of the risk of these procedures causing anatomic alterations, making it impossible to determine if these changes preceded embalming.

(8) Universal precautions are to be exercised at all times.

(9) Post-mortem examinations (normally encompassing both gross and microscopic studies) are to be conducted in a professional manner. The objective of these examinations is the full exposition of the patient's disease processes, the limits thereof, and the patient's response to therapy.

(a) The body is to be left in the best possible condition.

(b) Special examinations, when specifically authorized, need to be coordinated with appropriate funeral directors and VA authorities, as indicated.

(c) Authorization for removal of organ, or tissue, for donation is accomplished by completion of SF 523B, Authorization for Tissue Donation.

(10) Photographic documentation, an essential component of the post-mortem examination, needs to be readily available.

d. **Post-mortem Reports**

(1) Within 24 hours (72 hours for weekends and holidays), provisional anatomic diagnoses must be placed into VistA for hospital personnel to view, with a copy forwarded to the Chief or Director of the appropriate clinical service, and communicated to the patient's provider.

(2) The Chief or Director, Pathology and Laboratory Medicine Service, is responsible for establishing and maintaining a system for coding diagnoses, thereby enabling retrieval and compilation of cases in VistA. Final post-mortem examination diagnoses must be coded using SNOMED.

(3) SF 503, Post-mortem Protocol (paper or electronic version), must be used as the face sheet on all completed post-mortem examinations.

(a) The completed post-mortem examination, with final copy of succeeding pages, must be made a part of the patient's medical record within 30 days, unless exceptions for special studies are established by the medical staff.

(b) 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 on the SF 503.

(4) The following form of the post-mortem examination protocol is suggested as likely to correspond to clinical interest:

(a) Clinical diagnoses;

(b) Final anatomic diagnoses, including neuropathologic findings;

- (c) Gross and microscopic findings, including clinical summary;
- (d) Discussion to correlate clinical and post-mortem information;
- (e) Completion of quality assurance survey; and
- (f) Draft of lay letter to next-of-kin, if requested.

(5) Only a qualified licensed pathologist, board certified in anatomic pathology, can provide a final written diagnosis for gross and microscopic post-mortem examination findings.

(6) The Chief or Director, Pathology and Laboratory Medicine Service, is responsible for providing data on post-mortem examination findings to the clinical service chiefs or directors for use in their systematic internal reviews. The Chief or Director, Pathology and Laboratory Medicine Service, or appropriate pathologist, must present post-mortem examination findings at appropriate medical staff conferences.

(7) The original SF 503, with all succeeding pages, must be included in the patient's medical record, and a copy of the post-mortem report (paper or electronic) must be retained by the Pathology and Laboratory Medicine Service.

(8) The Chief or Director, Pathology and Laboratory Medicine Service, must provide the Chief of Staff or Director of Clinical Services for the medical facility with a copy of the post-mortem examination report in any case in which the post-mortem examination findings raise the possibility of a claim against VA.

(9) Post-mortem examination findings may be disclosed in accordance with the limited disclosure provisions of 38 U.S.C. Section 5705. In any case where there is a potential claim, no action is to be taken to release information without first consulting with the Regional Counsel.

**e. Recovery of Pacemakers or Implantable Defibrillators and Procedures for Returning or Disposing of These Devices**

(1) Veterans with pacemakers and other implantable devices are registered using the National Pacemaker and Device Registry at the VA Medical Center, Washington, DC.

(a) Explanted pacemakers, which are removed because of evidence of unexplained clinical failure or because of a FDA recall, must be sent by the Chief or Director, Acquisition and Materiel Management Service (A&MM) Service of VA medical centers, to the Eastern Cardiac Pacemaker Surveillance Center, VA Medical Center, 50 Irving Street, NW, Washington, DC, 20422. The explanted pacemaker is to be accompanied by a completed VA Form 10-0049, Explanted Cardiac Pacemaker Prosthesis (ECP) Data. A shipping label and a request for reimbursement by the manufacturer must be provided.

(b) Explanted pacemakers removed due to replacement or cremation can be tested locally and returned to the manufacturer for credit or sent in accordance with subparagraph 13e(1)(a). If

an individual medical center lacks the capability to evaluate an explanted model, it should be returned as stated in subparagraph 13e(1)(a).

(c) All VA medical centers need to ensure that credit is sought for explanted pacemakers still under warranty. If sent to the Eastern Cardiac Pacemaker Surveillance Center, the medical centers must use the mailing label provided and must include the request for reimbursement. A report on the operating characteristics of the explanted pacemaker must be sent to the originating VA medical center, to the manufacturer, and to FDA. If evaluated at the individual medical center, the pacemaker is to be returned directly to the manufacturer for possible credit. All generators are to be non-invasively analyzed so that VA can obtain credits toward new devices.

(d) In all cases in which the pulse generator is not removed from the body, SF 523 must clearly state its presence. For example:

**“NOTE: BODY CONTAINS A PACEMAKER WHICH INCLUDES A BATTERY OR POWER SOURCE”**

(2) **Cremation.** When an autopsy is performed, the SF 523 must document the removal of the pacemaker. When no autopsy is performed, the Chief or Director, Pathology and Laboratory Medicine Service, or designee, must seek authorization (and must document this on SF 507, Clinical Record Report) from the family to remove the pulse generator. *NOTE: Pathology needs to dispose of generators as required by the medical center's Biomedical Engineering Section.*

**f. Quality Improvement in the Post-mortem Examination Service**

(1) Performance standards must be established by the Chief or Director, Pathology and Laboratory Medicine Service, at each medical facility to ensure the:

(a) Pathologists' skills are sufficient,

(b) Post-mortem examination is performed accurately, and

(c) Post-mortem examination report addresses the questions of clinical concern to the patient's health care provider.

(2) The post-mortem examination can be used as an outcome measure to assess clinical diagnostic accuracy (see App. B).

**g. Use of Post-mortem Examination Tissues for Diagnostic, Scientific, or Therapeutic Purposes.** The SF 523 makes provision for the removal and retention of tissues for diagnostic, scientific or therapeutic purposes.

(1) If the autopsy procedure is to include the removal of tissues not covered by permits in the VA medical center, a SF 523B must be executed by the person authorized to grant permission for autopsy.

(2) Special permission must be obtained for removal of organs and tissues for transplantation.

(3) Research using tissues or organs removed at autopsy must be in conformity with a written protocol approved by the local Research and Development Committee and by its Subcommittee on Human Studies before the research begins.

#### **h. Confidential Treatment of Post-mortem Examination Records**

(1) If tissues or records are to be sent from VA for examination in non-VA laboratories or by investigators, such persons can be given access to such items only within the restrictions imposed by laws governing the disclosure of information, e.g., the Privacy Act of 1974, 38 U.S.C. Sections 5701, 5705, and 7332.

(2) Some of the preceding statutes address the disclosure of information about patients in an individual identifiable format. If the examiner requires that the slides and records contain the veteran's name or other confidential information, there must be a prior written agreement that:

(a) The recipient of the slides and records will not disclose any information in an identifiable form without prior specific VA authorization;

(b) Information will be safeguarded from disclosure; and

(c) The slides and records will be returned to VA when there is no longer a need for the recipient to retain them in order to accomplish the purpose for which they were originally supplied.

(3) When it is necessary to release records or slides in a manner other than that defined, the Regional Counsel needs to be consulted prior to the release.

(4) Specimens may be retained after completion of the post-mortem examination and presented at conferences. Cases with unusual findings may be sent to the Armed Forces Institute of Pathology as a consultation case.

(5) Use of photographs to record gross and microscopic features is encouraged. Files of photographs are to be retained as long as they are considered to be useful.

(6) Museum specimens, post-mortem materials retained for authorized research projects, and organized teaching collections may be exempted from the retention provisions.

## **12. ARMED FORCES INSTITUTE OF PATHOLOGY REFERENCE LABORATORY SERVICES**

a. **Scope.** This paragraph provides direction and guidance to VA medical facilities regarding the use of Armed Forces Institute of Pathology reference laboratories. Laboratories where

surgical specimens are examined are expected to participate in the Armed Forces Institute of Pathology SERS Program.

b. **Armed Forces Institute of Pathology.** Special arrangements have been established by VHA Central Office with the Armed Forces Institute of Pathology for anatomic pathology. When using these arrangements, the Armed Forces Institute of Pathology requires that the Armed Forces Institute of Pathology Form 288-R, Contributor's Consultation Request, with the appropriate category block checked, accompany all cases. These arrangements must include:

(1) **Quality Assessment Programs.** The Quality Assessment Program includes:

(a) The SERS Program.

1. All cases for quality assessment need to be selected by organ system on a scheduled basis rather than a random selection process.

2. The organ systems chosen need to correspond to the most frequent sources of surgical pathology accessions in VA, as well as the most referrals seen by Armed Forces Institute of Pathology under the present SERS Program.

(b) Support of the VA-Armed Forces Institute of Pathology Histopathology Quality Assessment Program.

(2) **Consulting Services.** The Special Reference Laboratory for Pathology at Armed Forces Institute of Pathology for VA provides consultation services on surgical and autopsy material, when requested, to include:

(a) Consultation services on central nervous system (brain) specimens (including enucleated eyes).

(b) Consultation services on muscle and peripheral nerve specimens.

(c) Consultation services on general surgical and autopsy specimens.

(d) Telepathology consultation services on any type of specimen.

(e) Crystallographic studies of tissue.

(3) **Other Relationships Between VA and Armed Forces Institute of Pathology.** Other relationships existing between VA and Armed Forces Institute of Pathology include:

(a) Reduced tuition fees to VA pathologists for Armed Forces Institute of Pathology Continuing Medical Education Programs.

(b) Routine contributions of specimens to the Armed Forces Institute of Pathology Special Registries (i.e., POW, Radiation, Gulf War, etc.) 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 the Armed Forces Institute of Pathology and VA. Unless specifically requested, routine diagnostic consultative reports from the Armed Forces Institute of Pathology are not sent to VA for specimens contributed to the Special Registries.

(4) **Channels of Communication.** Direct correspondence between VA pathologists and Armed Forces Institute of Pathology is authorized. All such communications must be addressed to the Director, Armed Forces Institute of Pathology, 6825 16th Street NW, Washington, DC 20306-6000.

(5) **Selection of Cases and Preparation of Material for Transmission to Armed Forces Institute of Pathology**

(a) Consultation Service. VA pathologists may send surgical material cases to Armed Forces Institute of Pathology for consultation when the opinion of the Armed Forces Institute of Pathology staff is needed to assist in reaching a diagnosis.

1. A completed SF 515, including the VA pathologist's diagnosis and indicating the points on which consultations are sought, must accompany all cases.

2. Armed Forces Institute of Pathology Form 288-R must accompany all requests.

3. Cases may be shipped individually as the need for consultation arises. In accordance with the urgency, cases must be marked "Telegram," "Rush," or "Routine;" the Director, Armed Forces Institute of Pathology, has agreed to send a prompt written consultation report on each such case. Consultation service autopsy cases need to be clearly identified on the Armed Forces Institute of Pathology accession to distinguish them from the SERS cases reviewed routinely in accordance with the following subparagraph 13e(5)(b), and to distinguish them from materials being contributed to the Armed Forces Institute of Pathology Special Registries.

(b) SERS Program

1. The Chief or Director, Pathology and Laboratory Medicine Service, at each VA medical facility where surgical and cytology specimens are examined, must select and forward to Armed Forces Institute of Pathology three significant surgical pathology cases every other month for a total of 18 cases a year. The cases selected need to be from material accessioned during the preceding 12 months. For example, cases selected for examination at Armed Forces Institute of Pathology for January needs to be from the skin, gastrointestinal system, and pulmonary system. If a surgical case has related cytology material, this material must be forwarded with the case. The cases are to be shipped to Armed Forces Institute of Pathology no later than the last working day of December, February, April, June, August, and October, in order to arrive during the month scheduled for SERS cases to be reviewed (see App. D for the SERS Schedule for Examination of Cases).

2. Selection of cases is at the discretion of the Chief or Director, Pathology and Laboratory Medicine Service, but the work of each pathologist must be reviewed in this Quality Assurance process. **NOTE:** For example, if there are four pathologists performing surgical pathology

*examinations, the Chief or Director must ensure that an equal number of cases from each pathologist is sent to Armed Forces Institute of Pathology over a 1-year period. The purpose of the program is to assess the quality of diagnosis for the service as a whole, as well as the quality of each pathologist's diagnosis.*

3. Cases must be identified by stamping or writing in block letters "SERS" in the upper right corner of SF 515. Complete the Armed Forces Institute of Pathology Form 288-R, and make sure the SERS block under Category "Rush," "Express mail," or "routine," is checked appropriately.

4. Each case must consist of a completed SF 515, a set of stained slides and, when feasible, blocks or wet tissue, as appropriate. **NOTE:** *Inclusion of photographs and X-rays is encouraged for review. The original is returned.*

5. The Armed Forces Institute of Pathology must respond within 30 days to all SERS cases with comments on significant features. Quarterly reports of participation by VA medical centers are provided by Armed Forces Institute of Pathology to the Chief Consultant, Diagnostic Services SHG, VHA Central Office, 810 Vermont Avenue, NW, Washington, DC 20420.

#### **(6) Cases of Special Interest, Eenucleated Eyes, and Related Specimens**

(a) VA pathologists may send cases of unusual interest to Armed Forces Institute of Pathology. Generally, such cases are forwarded because they may be of value to the pathology registries.

(b) Eenucleated eyes may be forwarded to the Armed Forces Institute of Pathology after fixation in 10 percent buffered formalin without further processing.

(c) Material may be sent to Armed Forces Institute of Pathology because of participation in a VA-Armed Forces Institute of Pathology cooperative research study.

**(7) Specific Reference Services and Special Registries at Armed Forces Institute of Pathology.** Specific Reference Services and Special Registries at Armed Forces Institute of Pathology include:

(a) Former POW, Agent Orange, and Gulf War Registries. A special Former POW Registry was established in 1980 at Armed Forces Institute of Pathology for pathological material from former POW's of World War II (WWII), the Korean Conflict, Vietnam Era, and subsequently, the Gulf War.

1. Each VA medical center must examine and report the findings of pathological material (surgical, cytologic, and autopsy) from POWs and Gulf War veterans in the customary manner.

2. After examination at the local VA medical center a duplicate set of slides, blocks, and representative wet tissue is to be forwarded to Armed Forces Institute of Pathology.

3. All material for shipment to Armed Forces Institute of Pathology must be packaged in the usual manner and addressed to: Director, Armed Forces Institute of Pathology, "Attention Former POW Registry, Agent Orange, or Gulf War Registry," as appropriate.

4. The Registry block needs to be checked on Armed Forces Institute of Pathology Form 288-R.

5. Routine diagnostic consultative reports from Armed Forces Institute of Pathology are provided to VA for specimens contributed to the Special Registries, unless such specimens are concurrently submitted as consultation cases and reports on these specimens are requested.

(b) Brain Biopsy Service. On request of interested VA pathologists, the Armed Forces Institute of Pathology supplies explicit directions for collection of specimens and containers filled with appropriate fixative. A written report will be sent promptly to the referring VA pathologist.

(c) Muscle Biopsy Service. On request of interested VA pathologists, the Armed Forces Institute of Pathology supplies explicit directions for the collection of specimens and containers filled with appropriate fixative. A written report is sent promptly to the referring VA pathologist.

(d) Crystallographic Studies. VA pathologists desiring special crystallographic studies on surgical or autopsy specimens must contact the Armed Forces Institute of Pathology for special instructions regarding preservation and shipment of specimens. VA pathologists must indicate clearly on the SF 515 or the SF 503 that accompanies the case, that crystallographic studies are required. *NOTE: A written report on each case must be sent to the referring VA pathologist.*

**(8) The Quarterly VA-Armed Forces Institute of Pathology Histopathology Quality Assessment Program.** The Quarterly VA-Armed Forces Institute of Pathology Histopathology Quality Assessment Program (HQAP) operates as follows:

(a) All Pathology and Laboratory Medicine Services providing histopathological services must participate in the program.

(b) In October, January, April, and July each year, the Armed Forces Institute of Pathology provides four histopathology quality assessment cases. Each case consists of a representative virtual microscopy stained slides, together with a brief clinical history. The Chief or Director, Pathology and Laboratory Medicine Service, must ensure examination of each case in the customary manner, which may include any regular local consultation, and return of the diagnosis to Armed Forces Institute of Pathology, by the date specified for each shipment.

(c) Armed Forces Institute of Pathology staff analyzes, for each quality assessment sample, all VA responses and groups them in accordance with the submitted diagnoses. A computerized tabular display of the diagnoses is developed at the Armed Forces Institute of Pathology with each VA health care facility identified only by a code number. Each display (together with the Armed Forces Institute of Pathology diagnosis), the opinions, when available, of outside recognized authorities, and a critique must be sent to each VA participant approximately 30 days

after receipt of responses. A copy of the display must be provided to the Chief Consultant, Diagnostic Services SHG, VHA Central Office.

(d) Continuing Medical Education (CME). One CME credit hour for each case reviewed is given to each pathologist who participates, up to a total of sixteen credits in 1 year.

(e) The Pathology and Laboratory Medicine Service National Surgical Pathology Committee monitors the program and determines which cases are appropriate for a quality assessment versus those cases that have educational value.

(9) **Reporting of Cases Sent to Armed Forces Institute of Pathology.** The Chief or Director, Pathology and Laboratory Medicine Service, must ensure that the number of surgicals and consultation cases sent to the Armed Forces Institute of Pathology are to be recorded appropriately in the workload recording module of the facility's VistA.

### 13. INFECTIOUS DISEASES, INFECTION CONTROL, AND EPIDEMIOLOGY

#### a. Scope

(1) This paragraph provides direction and guidance to VA medical facilities regarding infectious diseases, infection control, and epidemiology testing. **NOTE:** *Non-laboratory personnel often perform this testing.*

(2) All VA laboratories and Ancillary Testing Sites are required to:

(a) Comply with current VA directives and other applicable standards related to infection control.

(b) Facilitate infection control activities and investigations.

(c) Ensure that cost-effective culturing is implemented throughout the facility.

(d) Maintain the proper engineering controls, work practices, and the use of biological safety cabinets and personal protective equipment, where appropriate, in order to reduce the potential for aerosol spread of infectious microorganisms to patients, visitors, and VA employees.

(e) Investigate food-borne illnesses.

b. **Facility Infection Control Activities.** Infection control activities may be conducted by a functional group or an Infection Control Committee. This group provides oversight for the review of culture results, develops tolerance limits and intervention strategies, and develops corollary investigations when intervention is unsuccessful.

(1) **Representation.** Each main clinical laboratory must have a permanent representative on the facility Infection Control Committee. It is recommended that the Chief or Director, Pathology and Laboratory Medicine Service, the supervisor of the microbiology section (or other

laboratory personnel knowledgeable about environmental cultures, pseudoepidemics, and other microbiological phenomena) serve on the Infection Control Committee.

(2) **Reports.** Each laboratory must provide monthly reports to the Infection Control Committee or the facility Infection Control Officer. These reports need to include:

(a) Numbers and identification of microorganisms found in cultures with results of cumulative antibiotic susceptibility. *NOTE: An assessment of antibiotic resistance trends needs to be included.*

(b) Microorganisms that must be reported to local or State boards of health.

(c) Organisms that necessitate special isolation procedures (e.g., multiple antibiotic resistant organisms).

(d) Summary reports of dialysis water cultures performed in accordance with the latest version of the Association for the Advancement of Medical Instrumentation standard.

(e) Quarterly monitors for skin contaminants in blood cultures.

(f) Biological indicator (spore test) results on autoclaves throughout the facility.

(g) Results of infection control cultures, particularly Legionella as it is now an organizational Management of the Laboratory Environment standard for The Joint Commission.

(h) Results of potable water cultures that were analyzed in accordance with the relevant VA standard (see VHA Sup. to MP-3, Pt. I, Ch. 2, par. 2.16).

(i) Other total quality improvement reports, as appropriate.

c. **Food-Borne Illnesses.** If food-borne illness is suspected among VA employees or patients, the laboratory needs to consult the appropriate local, state, or Federal public health service laboratory for epidemiological and laboratory assistance.

## 14. BIOSECURITY AND BIOSAFETY PROCEDURES

### a. Scope

(1) All laboratories within VA that test patients for the diagnosis, treatment and prevention of disease must meet the applicable clinical laboratory requirements for handling select agents defined in 42 CFR 73 and 1003. These requirements are generally defined under 42 CFR 73 subpart 73.6.

(2) Where applicable, the laboratories must also meet any requirements for handling select agents, any security measures, hazardous materials and waste management measures, and emergency management procedures as defined by the following organizations: The Joint

Commission, CAP, AABB, Commission on Office Laboratory Accreditation (COLA), FDA, OSHA, Department of Transportation (DOT), and the NRC.

(3) In accordance with guidance previously described in paragraph 3, all clinical laboratory testing sites, regardless of location, must undergo an on-site inspection by a CMS and VA-approved accrediting agency.

(4) All applicable clinical laboratory requirements of 42 CFR 73, 1003, and appropriate accreditation standards must be met for any laboratory services offered within a VA medical facility and outreach clinics, regardless of the physical relationship to the main Pathology and Laboratory Medicine Service, or the administrative service assigned to direct the personnel, research, or technical aspects of the test site.

(5) Unless otherwise annotated, each Chief, Pathology and Laboratory Medicine Service is responsible for ensuring all laboratories under their direction are in compliance with the policy and regulatory requirements detailed in this Handbook.

#### b. Clinical Laboratory Standards

(1) **Laboratory Biosafety Level (BSL).** The CDC defines a biohazard as: "An agent of biological origin that has the capacity to produce deleterious effects on humans, i.e., microorganisms, toxins, and allergens derived from those organisms; and allergens and toxins derived from higher plants and animals." The following four basic classifications for these biohazards are defined as:

(a) BSL-1, i.e., agents not known to cause disease.

(b) BSL-2, i.e., agents associated with human disease.

(c) BSL-3, i.e., indigenous or exotic agents associated with human disease and with potential for aerosol transmission.

(d) BSL-4, i.e., dangerous or exotic agents of a life threatening nature.

(2) **Biological Safety Cabinets.** Biological safety cabinets are broken down into three basic types: Class I; Class II; and Class III. These cabinets are designed to protect laboratory personnel from aerosols created in handling and manipulating biological agents. The cabinets afford increasing protection as the class of the cabinet increases and the required class of the cabinet is selected based upon the hazard of the agent, the need for protection of personnel, and the extent to which aerosols may be produced. For most microbiological organisms encountered in clinical laboratories, generally a Class I or Class II cabinet is more than adequate.

(a) Since control of any aerosols produced depends upon proper biological safety cabinet performance, certification is necessary:

1. At initial installation and annually;

2. After moving a cabinet; and
3. After replacing a high efficiency particulate air (HEPA) filter.

(b) The certification procedure must include:

1. A leak test to ensure the air flow plenums are gas tight;
2. Measuring the air inflow velocity;
3. Measuring the airflow within the cabinet (uniform and unidirectional); and
4. A leak test of the HEPA filter to ensure that it is properly installed and leak-free.

*NOTE: Under no circumstances should a biological safety cabinet ever be moved or the filter changed without the cabinet and ductwork being properly decontaminated. The cabinet is never to be placed back into service, unless it has been properly certified.*

(3) **Requirements and Personnel Standards.** The laboratory requirements and personnel standards are defined for each of the four basic classifications and increasingly stringent for the laboratories from BSL-1 through BSL-4. A combination of administrative controls, engineering controls and personal protective equipment may be used to minimize employee exposure to biohazardous materials in the laboratory setting. An applicable reference that defines the specific laboratory requirements for each BSL is the fifth edition of the CDC and National Institutes of Health (NIH) Biosafety in Microbiological and Biomedical Laboratories (the CDC-NIH Manual).

(4) **BSL-3 Practices**

(a) All existing VA laboratories performing diagnostic procedures involving the propagation of an agent that calls for BSL-3 practices for identification, typing, and susceptibility must be fully BSL-3 compliant or must cease such operations.

(b) All new laboratory sites implementing identification and testing procedures that require BSL-3 practices must not implement such procedures until the facility meets the full BSL-3 requirements.

(5) **General Laboratory Procedures for Culturing Patient Specimens.** Any clinical laboratory routinely culturing patient specimens for microbiological organisms must meet as a minimum, the BSL-2 facility and personnel training requirements defined in the CDC-NIH Manual.

(6) **Laboratory Procedures for Performing Acid Fast Stains.** As only BSL-2 practices and procedures are required for non-aerosol-producing manipulations of clinical specimens, such as preparation of acid-fast (AFB) smears for *Mycobacterium tuberculosis* (MTB), it is acceptable to carry out direct AFB smear staining procedures in a BSL-2 laboratory. Due to the risk of aerosols, any AFB smears prepared in a BSL-2 laboratory must, however, be limited to direct

AFB smears only. Concentrated AFB smears are only to be prepared in a properly certified BSL-3 laboratory.

(7) **Laboratory Procedures Associated With Aerosol Transmission.** BSL-3 organisms as defined by the CDC, such as *Histoplasma*, *Coccidioides*, *Blastomyces*, and *Mycobacterium tuberculosis*, are potentially infectious to laboratory workers and staff, visitors, and patients of the medical facility by virtue of aerosol dissemination. Employee screening, engineering controls, and personal protective equipment, as described in the following, can minimize the dangers.

(a) At low-exposure facilities (one that isolates and identifies cultures of any BSL-3 organisms from six or fewer patients per year), laboratory employees who are potentially exposed to *Mycobacterium tuberculosis* must be tested for exposure to this organism every year.

(b) At high-exposure facilities (one that isolates and identifies cultures of any BSL-3 organisms from more than six patients per year), laboratory employees who are potentially exposed to *Mycobacterium tuberculosis* must be tested for exposure to this organism every 6 months.

(c) In laboratories that routinely work with bacterial agents such as *Mycobacterium tuberculosis* in culture or with cultures that yield *Histoplasma capsulatum*, *Coccidioides immitis*, *Blastomyces dermatitidis*, or other BSL-3 agents, both the design and operation of the facility must adhere to the full BSL-3 facility requirements detailed in the CDC-NIH Manual.

c. **Site Requirements for Handling Select Agents**

(1) **Select Agents Potentially Encountered in Clinical Laboratories.** In 42 CFR 73, a number of select agents and toxins are identified. However, the majority of these agents and toxins are not routinely encountered in most clinical laboratories. The agents of most relevance to clinical laboratories are the six pathogens designated by the CDC as “Category A” diseases or agents. These are the organisms or toxins that are believed to pose the most risk to national security, as they may be easily cultured or acquired and could result in high- mortality rates or cause public panic. These Category A agents include *Bacillus anthracis*, *Clostridium botulinum* toxin, *Brucella species (abortus, melitensis, and suis)*, *Yersina pestis*, smallpox (variola major), *Francisella tularensis*, and the agents causing viral hemorrhagic fevers (i.e., Ebola and Marburg viruses).

(2) **Select Agent Handling Requirements.** Special procedures are detailed in 42 CFR 73 and by CDC for culturing and handling these select agents. Those procedures applicable for clinical laboratories are summarized at follows: **NOTE:** *Current additional information can also be found on the CDC Select Agent Program website at: <http://www.cdc.gov/od/sap/>.*

(a) The clinical laboratory must immediately report to HHS any select agent or toxin identified as a result of diagnosis or verification.

(b) Any reports required under applicable Federal, State, or local laws must also be immediately initiated.

(c) Upon completion of applicable patient and proficiency testing or transfer of the select agent to a facility eligible to receive them, the laboratory must appropriately destroy the culture or toxin and document the steps taken in this process.

(d) The clinical laboratory is required to safely transfer or destroy the select agent or toxins used for diagnosis or testing within 7 days after identification unless directed otherwise by Federal or other law enforcement officials. Any stock culture maintained during work-up for isolates referred to an outside laboratory for identification and that has been positively identified as a select agent, must be destroyed within 7 days of notification of these findings.

(e) Select agents or toxins used for proficiency testing must be transferred or destroyed within 90 days after receipt.

(f) A record of the identification, transfer, or destruction of select agents must be documented on the appropriate CDC form and submitted to HHS within the time specified. Copies of these records must be maintained for a specified period. *NOTE: At the time of the publication of this handbook, CDC Form 0.1318 (CDC Form EA-101) is being used for documentation; 7 days after identification is the time specified for transfer or destruction; and all documents must be retained for a period of 2 years.*

(3) **Security Requirements.** By design, clinical laboratories are open and accessible to clinicians and other members of the medical staff. Providers often come into the laboratory to review slides, other clinical materials, or to consult with the laboratory staff. While it is important to maintain an appropriate level of access, certain changes must be made in order to ensure that access to select agents is appropriately restricted.

(a) Department physical security requirements are codified in VA Directive 0730 and VA Handbook 0730. A memorandum modifying this handbook to meet the new clinical and research laboratory security requirements was disseminated on July 29, 2002. Until VA Handbook 0730 is republished, this memorandum serves as the interim guiding document. Specific requirements are found in Appendix B of this Handbook. Areas where bio-hazardous materials, as defined by the CDC, are stored is found under the standards K, L, and M of the VA Handbook 0730, Appendix B matrix. The facility director, responsible for general facility security, must ensure that applicable facility modifications and other security measures defined in VA Directive 0730 and VA Handbook 0730 have been implemented.

(b) Any of the select agent organisms that are not absolutely required for patient care, PT, or educational purposes must be destroyed and the destruction documented. Once cultures of the listed organisms are identified, a clear audit trail must be maintained.

(c) In general, only select agent organisms that are cultured from VA patients or stock cultures that are necessary for ongoing quality control or PT purposes need to be retained.

(d) Once patient specimens and cultures have been determined to contain any select agent organisms, they must be secured under lock and key anytime they are not being actively worked up or being left unattended.

(e) Access to the incubation, refrigeration, freezer, or other storage and work up areas for these select agents must only be accessible to authorized personnel.

(f) Clearly it would be prudent to restrict access to certain other high-risk areas of the laboratory that contain radioactive, toxic or infectious materials. While many laboratories are already doing this, it also seems reasonable to conduct regular reviews and to revise laboratory specific security plans in conjunction with the facility's overall plan. Each Chief, Pathology and Laboratory Medicine Service must ensure a laboratory risk assessment is conducted, a security plan is developed, and that local laboratory policies governing personnel and security procedures are well documented.

(g) Procedures for defining an approval process and updated lists for access to specific rooms or areas, procedures for security during "low-staffing" periods, notification procedures, etc., must be addressed.

(h) Added video surveillance may be applicable and may be of value for some clinical laboratories.

(i) Added security personnel may be required, particularly at some of the larger sites, to monitor and register personnel entering and leaving the laboratory. *NOTE: If added security measures are required (and due to the already constrained laboratory personnel resources) these general duties could be carried out, in most instances, by security guards.*

#### d. Shipping Biological and Infectious Substances

(1) **Regulatory Requirements.** The regulations governing the packaging and shipment of biological, infectious, and hazardous substances are primarily found in 49 CFR parts 100-185 and 397. The parts of 49 CFR specifically dealing with biological and infectious specimens are 107, 171, 172, and 173. While the majority of shipments packaged and processed by the clinical laboratories are classified as diagnostic specimens, all specimens, as well as any select agents and toxins that are identified, must be packed and shipped in accordance with the applicable guidance provided in 49 CFR.

(2) **Hazardous Materials and Security Training.** Personnel shipping hazardous materials (hazmat) must be aware of the potential use of hazmat for acts of terrorism and are required to have documented transportation security awareness training. As many biological specimens are now classified as hazmat, it is important for all laboratory personnel that are involved in the packing and shipping of laboratory specimens to have hazmat training. While a number of commercial training programs are available, which will satisfy this requirement, a free training program is available from the DOT web site at [http://hazmat.dot.gov/hmt\\_security.htm](http://hazmat.dot.gov/hmt_security.htm). It is the responsibility of each Chief, Pathology and Laboratory Medicine Service to ensure that all personnel who deal with specimen transportation and shipment receive this training.

## 15. ENVIRONMENTAL AND SAFETY ISSUES IN THE LABORATORY

### a. Scope

(1) This paragraph provides laboratory safety information to assist laboratories in designing complete safety programs in accordance with the requirements of VA and other Federal agencies.

(2) VA Manual MP-3, Part III, Safety, Occupational Health and Fire Protection, outlines VA policy for safety, occupational health and fire protection. The laboratory safety program must be in full compliance with the requirements of the Occupational Safety and Health Act of 1970 (29 CFR Part 1910), Executive Order (E.O.) 11807, and guidelines issued by the Secretary of Labor under Section 3 of this Order. Further, each laboratory must have a designated Safety Officer.

### b. Laboratory Safety Program

(1) The Chief or Director, Pathology and Laboratory Medicine Service, must ensure that a written safety program is developed and implemented which is in compliance with the requirements of VA policies, 29 CFR Part 1910, OSHA; 21 CFR Part 801, FDA; 49 CFR Part 172, DOT; 42 CFR 493, CMS; NRC; International Air Transport Association (IATA); The Joint Commission; CAP; AABB, or other applicable regulations or accreditation guidelines.

(2) The safety program includes: a safety manual, a Chemical Hygiene Plan (CHP) written in accordance with OSHA regulations (29 CFR 1910.1450, App. A); bloodborne pathogen and tuberculosis exposure control plans; a latex safety program; training in shipping and handling of hazardous goods, including certification of personnel who ship infectious substances; and any other safety requirements identified by regulation or accreditation standards.

(a) The CHP mandated for every laboratory that uses hazardous chemicals must include:

1. All operations that involve hazardous chemicals;
2. Criteria for use of personnel protective equipment;
3. Criteria for exposure monitoring; and
4. Provisions for training employees in the CHP elements.

(b) The safety manual must include, at a minimum, the following procedures:

1. Reporting accidents, injuries, and illnesses;
2. Fire prevention and control;
3. Electrical safety;

4. Chemical hazards;
  5. Radiation hazards;
  6. Microbiologic hazards (including infection control policies); and
  7. Hazardous waste disposal.
- (c) The exposure control plan must be developed in accordance with 29 CFR 1910.1030.
- (3) A laboratory safety committee or the laboratory Safety Officer must:
- (a) Ensure periodic inspection of the workplace and prompt elimination of unsafe conditions;
  - (b) Review accident records;
  - (c) Ensure compliance with the safety program; and
  - (d) Report activities to the facility safety committee.

c. **Training.** All employees working within Pathology and Laboratory Medicine Service must receive laboratory safety training in accordance with the VA Occupational Safety and Health (OSH) Program, the Laboratory Safety Program, and applicable OSHA requirements.

## 16. ENFORCEMENT REQUIREMENTS

### a. **Scope**

(1) This paragraph provides direction and guidance to VA medical facilities regarding the enforcement of CLIA '88, i.e., Pub. L. 102-139.

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

b. **Pathology and Laboratory Medicine Service National Enforcement Office.** The Pathology and Laboratory Medicine Service National Enforcement Officer, with the assistance of the VA Pathology Regional Commissioners and Regional Technologists, is responsible for providing VA laboratories with the enforcement and oversight discussed in 42 CFR 493, Subpart R.

c. **VA Pathology Regional Commissioners.** The VA Pathology Regional Commissioners are responsible for:

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

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

(3) Ensuring that each Pathology and Laboratory Medicine Service has copies of VHA Handbooks and guidance documents dealing with laboratory inspection, accreditation requirements, and the proficiency programs.

(4) Providing appropriate oversight of inspections.

(5) Analyzing inspection reports from all laboratories in their respective regions to identify serious problems and trends and reporting this information to the Pathology and Laboratory Medicine Service National Enforcement Office and appropriate management officials.

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

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

(8) Reviewing investigation reports from the Joint Commission, CAP, FDA, AABB, Inspector General (IG), General Accountability Office (GAO), Medical Inspector (MI) dealing with Pathology and Laboratory Medicine Service in their region, and following up with the laboratory in question to ensure that identified problems are corrected in a timely fashion.

(9) Advising the Pathology and Laboratory Medicine Service National Laboratory Enforcement Officer of problems and concerns relating to the quality of the work in Pathology and Laboratory Medicine Service.

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

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

(12) Delegating responsibilities and functions to the Regional Technologist.

d. **Enforcement Procedures**

(1) **Definitions**

(a) **VA Laboratory.** Any laboratory or testing site that performs laboratory testing used in the diagnosis, treatment or assessment of patients (VA and non-VA) within a VA medical center and its affiliated testing sites is considered to be a VA laboratory and is required to operate in compliance with this Handbook; this includes laboratories or testing sites that are not under the direct control of the Chief or Director, Pathology and Laboratory Medicine Service.

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

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

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

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

(f) **Score.** To determine the score for the analyte testing event, the percent of acceptable analyte responses must be calculated as follows:

$$\frac{\text{Number samples or analyte correct}}{\text{Total Number samples or analyte}} \times 100$$

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

1. A score of 80 percent or greater for any analyte in an event which is composed of five samples (challenges).
2. A score of 100 percent in blood group and type (ABO/Rh), or compatibility testing.

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

(h) Unsatisfactory

1. Failure to attain a minimum satisfactory score on a single PT event described as follows:

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

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

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

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

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

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

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

3. Failure to return PT results to the PT provider within the time frame specified by the program is unsatisfactory performance and also results in a score of zero for the testing event.

*NOTE: The only exceptions may be for extraordinary circumstances or if the reason for the error is traceable to the PT provider.*

(i) Failure or Unsuccessful Participation. Failure or unsuccessful participation is described as follows:

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

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

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

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

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

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

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

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

(l) Corrective Action Plan. A Corrective Action Plan consists of:

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

2. Specific actions taken to prevent reoccurrence; and

3. Evidence that the problem has been corrected.

*NOTE: Failure in PT is further addressed in subparagraph 16d(2)(e).*

(2) **PT Program.** All VA laboratories that perform testing on patients (VA or non-VA) must participate in external PT programs and maintain successful performance for all tests for which there is a proficiency test. For those analytes or tests that do not have formal proficiency samples available, the laboratory or testing site must develop an in-house system to verify, at least twice a year, the accuracy of these test results.

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

(b) When a laboratory fails to submit the results of a survey or submits the results after the deadline, the laboratory receives a score of zero for the entire survey event, which puts the laboratory at risk of "Failure" for the next two surveys.

(c) If laboratories have second instruments (backup analyzers) or methods that are to be used for patient testing, the results from all instruments or methods must be included in the laboratory PT program. All of these tests systems must be evaluated for satisfactory performance.

(d) The VA Pathology Regional Commissioner maintains an ongoing review of all clinical pathology PT results from facilities within their respective regions, and other facilities as assigned.

(e) In the event of a PT failure for any analyte, the laboratory is required to implement the following procedures:

1. Cease testing for the particular analyte(s) on the suspect instrument.

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

3. The laboratory investigations performed must be thorough and include a review for clerical errors, technical or methodological issues, problems with the PT materials, Quality Control, and maintenance records, policies and procedures, interviews with staff, performance on previous PT surveys, etc. The corrective action plan and supporting documentation must specifically address the details of the investigation plus, if possible, the retesting of the PT challenges, an evaluation of patient results at the time of the unsatisfactory PT performance, any previous corrective action taken to prevent or minimize future recurrences, and any required staff education and training which must be documented as to date, material covered, and persons attending.

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

5. If no CMS-approved PT provider exists for the failed analyte, the affected laboratory and the VA Pathology Regional Commissioner's Office determines the most effective and efficient way of reinstating testing (i.e., a split sample may be sent to the laboratory's normal reference laboratory). The results from the reference laboratory need to be sent to the VA Pathology Regional Commissioner for review.

6. The VA Pathology Regional Commissioner must review a copy of the laboratory's corrective action (see subpar. 16d(2)(e)3), the results of the remedial testing, and supporting data. In addition, the Regional Commissioner may request additional corrective action, or the implementation of an additional training program as deemed appropriate. Testing may only resume when there is approval of the remedial testing and the laboratory's corrective action by the VA Pathology Regional Commissioner or the Pathology and Laboratory Medicine Service National Enforcement Office.

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

a. There is no immediate jeopardy to patient health and safety.

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

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

g. The laboratory, as part of their Quality Management program, must reassess the corrective action implemented periodically to ensure continued compliance to prevent the problem from reoccurring.

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

(g) An unsatisfactory testing event requires the laboratory to investigate the incident and, if possible, determine the problem and take appropriate corrective action. Documentation of the corrective action taken needs to be forwarded to the VA Pathology Regional Commissioner within 15 working days upon receipt of the PT evaluation report.

*NOTE: See subparagraphs 10d and 10e for QI and PT requirements for anatomic pathology services.*

**SAMPLE FORMAT FOR A FACILITY QUALITY PLAN**

*The following is a sample format that may be used to develop a quality plan; the quality plan gives an overall description of the Quality Improvement (QI) program for the Blood Bank and/or Transfusion Service. The laboratory must also implement support policies and procedures. For example, under the "Change Control" section, there is the following statement, "(1) The facility has a defined process for initiation, development, and implementation of any change in policies or procedures." The laboratory must also develop a standard operating procedure (SOP) that defines this process.*

**QUALITY POLICY OF THE (insert facility name) BLOOD BANK AND/OR TRANSFUSION SERVICE (choose one to insert here and in the following)**

**1. INTRODUCTION**

a. The (insert facility name) blood bank or transfusion service maintains a quality system which meets the regulatory requirements of the Food and Drug Administration (FDA), as well as the quality standards of (insert transfusion service) (e.g., the American Association of Blood Banks (AABB), College of American Pathologists (CAP), The Joint Commission.

*NOTE: Include whichever accrediting and peer review organizations are relevant for the individual facility.*

b. This Quality System supports the mission of the Department of Veterans Affairs (VA) to improve patient care through continuous quality improvement. To accomplish this, the Quality System strives to develop the highest quality processes, products, services, and personnel. The Quality System is designed to oversee the functions of the blood bank or transfusion service laboratory itself, as well as transfusion practices elsewhere in the medical center (use another term if more appropriate) and ancillary facilities (omit if irrelevant or specify these facilities). More specifically the goals of the (insert facility name) blood bank or transfusion service are to:

(1) Implement effective processes and systems controls to ensure the highest possible product quality, service quality, and patient safety;

(2) Detect and, most importantly, strive to prevent errors in transfusion practice;

(3) Reduce process variations that can cause errors;

(4) Improve the efficiency of processes without sacrificing quality or safety;

(5) Respond to customer needs for blood components and services;

(6) Develop and maintain competent staff; and

(7) Comply with all applicable regulations and accreditation standards.

c. The (insert facility name) blood bank or transfusion service strives to maintain the highest-quality standards through on-going self-monitoring of each of these components, customer feedback, and appropriate modifications to the Quality System, as necessary.

d. The (insert facility name) blood bank or transfusion service is a (small, moderate, large) facility with the following scope of operations: (Choose those that are applicable from the following list.)

- (1) Donor suitability;
- (2) Blood collection;
- (3) Component processing;
- (4) Donor testing;
- (5) Test result review and labeling;
- (6) Storage, distribution, and dispensing;
- (7) Confirmatory donor testing;
- (8) Recipient testing and compatibility testing;
- (9) Blood administration;
- (10) Investigation of adverse effects;
- (11) Information management;
- (12) Autologous transfusion (pre-operation, intra-operation, post-operation);
- (13) Apheresis (therapeutic, donor);
- (14) Tissue storage and dispensing;
- (15) Histocompatibility testing and organ transplantation; and
- (16) Hematopoietic progenitor cells.

**2. ORGANIZATION NOTE:** *Modifications may need to be made to the following depending on the size and scope of operations and the composition of personnel at the individual facility.*

a. The executive management is comprised of the *(insert the individuals who comprise your executive management, e.g., Chief, Pathology and Laboratory Medicine, the Medicine-Transfusion*

*Service Medical Director, the Chief Technologist, and the Hospital Transfusion Officer*). They report to \_\_\_(*insert the organizational contact, i.e .the hospital Chief of Staff*)\_\_\_.

b. The Chief or Director, Pathology and Laboratory Medicine Service, is responsible for the following related to transfusion medicine:

(1) Serves as the responsible head for the blood bank or transfusion service in all dealings with FDA and other accrediting agencies. **NOTE:** *A designee, e.g., the medical director, may be named here instead.*

(2) Promotes and supports continuous quality improvement activities.

(3) Reviews and approves the initial Quality System and on-going changes.

(4) Reviews the annual Quality Assurance Summary.

c. The Chief Technologist is responsible for:

(1) Hiring transfusion service employees.

(2) Management of human resource issues.

(3) Supervision of the general supervisor of the Transfusion Service.

d. A \_\_\_(supervisory or qualified technologist (choose one))\_\_\_ oversees the activities of the blood bank or transfusion service. This individual assumes primary responsibility for the:

(1) Oversight of day to day operations.

(2) Review of all work related to provision of blood components and services.

(3) Development, implementation, and maintenance of the facility's Quality Program (including the Quality System, policies, and procedures).

(4) Review of self-assessment and on-going monitors.

(5) Preparation of annual quality assurance summary.

e. A qualified pathologist appointed by the Chief or Director, Pathology and Laboratory Medicine Service, serves as medical director for the blood bank or transfusion service. This individual is responsible for:

(1) Providing general oversight for blood bank or transfusion service and transfusion practices throughout the facility.

(2) Providing consultation to other providers regarding appropriate transfusion practice.

(3) The development, implementation, and maintenance of the facility's Quality Program, including the Quality System policies and procedures in collaboration with the supervisory or qualified technologist.

(4) Reviewing and approving all blood bank or transfusion services policies and procedures before implementation, after any change, and on an annual basis. Any exceptions to policies, processes, or procedures warranted by clinical situations requires justification and pre-approval by the medical director on a case-by-case basis.

(5) Reviewing the annual Quality Assurance Summary before it is submitted to the Chief or Director, Pathology and Laboratory Medicine Service.

*NOTE: If the facility has no physician qualified to serve as medical director, the Chief or Director, Pathology and Laboratory Medicine Service, another pathologist or a clinician with expertise in this area (Transfusion Officer) may assume these responsibilities or they may be divided up in a specified manner.*

f. A \_\_\_(designated individual(s) (specify number, qualifications, and title)\_\_\_ is responsible for quality assurance in the blood bank or transfusion service area (hereafter referred to as the "Quality Unit"). This unit reports directly to the Chief or Director, Pathology and Laboratory Medicine Service. The "Quality Unit" is responsible for:

(1) Assisting in the development and maintenance of the Quality Program.

(2) Review and approval of initial Quality Program and on-going changes before submission to Chief or Director, Pathology and Laboratory Medicine Service.

(3) Assisting in the review of self-assessments and on-going monitors.

(4) Assisting in the preparation of the annual Quality Assurance (QA) Summary.

*NOTE: In some facilities there may be a QA group for the medical center as a whole and the reporting structure may be different; if this is the case, specify here.*

### 3. RESOURCES

The  (insert facility name)  blood bank or transfusion service employs an adequate number of individuals qualified by education and experience who are provided with adequate training to perform all assigned tasks and who are assessed periodically for on-going competence.

#### a. Personnel Selection

(1) Job descriptions are written and maintained for each position.

(2) Candidates must meet the qualifications defined in the job description, the Clinical Laboratory Improvement Amendments (CLIA'88), and Title 5 or Hybrid Title 38 United States Code (U.S.C.).

(3) Candidates must provide documentation of education, training, and experience relevant to the position for which they are being considered.

**b. Orientation and Training of New Employees**

(1) New employees are provided orientation to the facility, to the laboratory service, and to the blood bank or transfusion service.

(2) General training is provided in the areas of safety, infection control, and personnel-related issues.

(3) Job-specific training is provided in the performance of all assigned duties per the job description.

(4) Training is considered complete when the employee demonstrates sufficient knowledge and skill to perform all assigned tasks.

(5) Job-specific training is documented in a standardized format and the documentation is maintained in the blood bank or transfusion service files and the employee Human Resource Management Service (HRMS) Official Personnel File (OPF).

(6) Retraining is initiated when a need is identified through periodic competency assessment or other defined indicators.

**c. Competency Assessment**

(1) Competency assessment is designed to look at all phases of the employee's assigned tasks. The process is accomplished in a variety of ways, but always includes an element of direct observation and never relies only on proficiency testing samples. The tools used are identical for all individuals with the same job description.

(2) Competency is assessed as part of the job-specific training process, and is also performed after the first 6 months for new employees.

(3) Competency of all employees is assessed annually.

(4) Documentation of competency is maintained in a standardized format in the blood bank or transfusion service files.

(5) Inadequate performance on the competency assessment requires immediate and appropriate retraining.

d. **Performance Appraisals**

(1) Performance appraisals are performed at 6 months for new employees and annually thereafter.

(2) The appraisal is based on job accountability, pre-defined standards, performance on competency assessment, and other objective measures.

(3) Documentation is maintained in a standardized format as required by HRMS and maintained in the employee's OPF.

e. **Continuing Education and Staff Development**

(1) Continuing education is mandatory and must be made available to all employees.

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

(3) Documentation of these activities must be maintained.

f. **Trainer Qualification.** Selected individuals who meet predetermined qualifications, based on education or experience related to specific tasks, function as trainers for the blood bank or transfusion service.

**4. EQUIPMENT**

The (insert facility name) blood bank or transfusion service is responsible for ensuring that each new piece of equipment meets expected performance standards and for maintaining a program of calibration, preventive maintenance, and quality control appropriate for each type of equipment.

a. **Selection of New Equipment**

(1) The blood bank or transfusion service staff plays an active role in the selection of new laboratory equipment for purchase by the medical center.

(2) Specifications for each item are defined and each supplier's ability to meet these requirements assessed before any new piece of equipment is selected for purchase.

(a) **Installation.** Each piece of new equipment is installed according to manufacturer's recommendations and with the help of the supplier, if appropriate.

(b) **Validation.** When a new piece of equipment is obtained, testing is performed to document that the equipment meets the manufacturer's published performance standards (FDA, Title 21 Code of Federal Regulations (CFR) Part 211 and Part 606, AABB standards, and CLIA '88).

b. **Calibration**

(1) Calibration is performed on all measuring devices used in critical processes and all equipment used in providing patient services including (insert relevant equipment, e.g., blood warmers, apheresis equipment, intra-operative salvage devices, etc.).

(2) Calibration is performed on all new equipment, after each repair, and on a schedule in conformance with all regulatory requirements and accreditation standards.

(3) Calibration is performed according to procedures defined by the manufacturer.

(4) Calibration documentation is maintained, including equipment identification (ID), calibration results, actions taken (i.e., equipment disposition), and follow-up.

c. **Preventive Maintenance**

(1) Preventive maintenance is performed on each type of equipment based on the manufacturer's recommendations, regulatory requirements, accreditation standards, and internal requirements.

(2) Preventive maintenance is performed on a schedule which meets manufacturer recommendations, all applicable regulatory requirements, and accreditation standards.

(3) Preventive maintenance documentation is maintained, including equipment ID, preventive maintenance results, actions taken (i.e., equipment disposition), and follow-up.

d. **Quality Control**

(1) Quality control is performed on each type of equipment based on manufacturer's recommendations, regulatory requirements, accreditation standards, and internal requirements.

(2) Quality control documentation is maintained, including equipment ID, quality control results, actions taken, and equipment disposition.

e. **Defective Equipment.** Any defective equipment must be temporarily removed from service and evaluated. All defective equipment must be properly labeled. After repair, all equipment must be calibrated before use. If the equipment cannot be repaired, it must be discarded properly.

f. **Establishment of Facility Specific Normal Range**

(1) A normal range (reference range) is established, or validated, before a new methodology is implemented when a new piece of equipment is placed in use and whenever there is a significant change in reagents.

(2) The reference range established must be applicable to the population being tested at the facility.

(3) The number of samples used to establish or validate the reference range must be based on manufacturer's recommendations and must meet all applicable regulatory requirements and accreditation standards.

## 5. SUPPLIER AND CUSTOMER ISSUES

The (insert facility name) blood bank or transfusion service and Acquisition and Materiel Management Service work together to maintain a system that ensures that suppliers of equipment, supplies, and services which have a critical impact on product quality, service quality, and safety meet predetermined specifications.

### a. Supplier Qualification

(1) Desired characteristics and functional requirements for critical supplies, blood components, and blood services are defined by the blood bank or transfusion service.

(2) Each new supplier is assessed for its ability to meet the requirements before selection.

(3) Existing suppliers are monitored for performance.

(4) An approved supplier and vendor listing is maintained.

### b. Contract Review

(1) Contracts are reviewed in accordance with the Federal Procurement Regulations.

(2) To ensure that service requirements and quality standards are met, a blood bank or transfusion service representative participates in the review of all new contracts and any contract changes that have any impact on the blood bank or transfusion service.

### c. Receipt, Inspection, and Testing of Incoming Supplies

(1) The facility maintains a system to inspect incoming critical materials and blood components for integrity and quality.

(a) This process is performed based on established acceptance criteria for each material or component.

(b) These inspections are documented in such a manner that recurrent problems are detected.

(2) Supplies or services not meeting established acceptance criteria are quarantined or temporarily suspended pending evaluation. Documentation is maintained for all critical supplies that are discarded or returned to supplier.

## 6. PROCESS CONTROL

a. **Standard Operating Procedure (SOP) Manuals.** In order to provide standardization and minimize variation and error in the blood bank or transfusion service, the facility develops and maintains a comprehensive policy and SOP manual covering critical functions (technical, clerical, administrative) performed by the facility.

(1) The facility uses a standardized approach for the development and writing of SOPs.

(2) The SOP manual must be current in order to reflect the actual practices in the facility.

(3) Operator's manuals, manufacturer's package inserts, or textbook procedures are not used in place of the written procedure, but may be included in the body of the manual.

(4) The SOP manual is readily available to all staff in the blood bank or transfusion service.

(5) The blood bank or transfusion medicine supervisory technologist or medical director approval is required for any deviation from SOP and justification for such deviations must be documented.

b. **Process and Procedure Validation Activities.** The (insert facility name) blood bank or transfusion service validates its critical processes to ensure that these processes are efficient and will consistently produce a quality product or service, meeting pre-defined standards. This includes validation of administrative and technical processes, computer hardware, and computer software. The method and extent of validation performed depends on the complexity of the process and on how critical an impact the particular process has on product or service quality or safety.

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

(2) Prospective validation is performed for new and complex processes, which impact areas outside the blood bank or transfusion service and which have a critical impact on product or service quality or safety. Training is provided for all personnel impacted. The process is then piloted, results reviewed, and procedural changes made as necessary before the process is formally implemented.

(3) New technical procedures are prospectively verified by the impacted individuals in the blood bank or transfusion service.

(4) Concurrent verification is performed for simple, new administrative procedures or for minor changes in more complex administrative procedures. Results are reviewed promptly, as they become available, and changes made to the procedure, as needed.

(5) Revalidation is performed when process changes occur which could affect the process outcome.

c. **Change Control**

(1) The facility has a defined process for initiation, development, and implementation of any change in policies or procedures.

(2) Before implementation, all changes must be approved by the blood bank or transfusion service supervisory technologist and medical director.

(3) At a minimum, the change control records need to include:

- (a) A description of the change, the date of the change,
- (b) The person making the change,
- (c) Equipment or other functions that are affected by the change,
- (d) An authorization signature,
- (e) The validation risk assessment, and
- (f) The documentation of approval and acceptance.

(4) Documentation of all changes, including dates, is maintained.

(5) Training on the change must be provided to all personnel, as appropriate.

d. **Reagent Quality Control.** Reagents used by the bank or transfusion service must meet or exceed FDA requirements. All materials must be stored and used in accordance with the manufacturer's specified instructions. Documentation must be maintained of all testing performed

(1) **FDA-licensed Reagents.** For FDA-licensed reagents, quality assurance testing is performed each day of use, per the manufacturer's recommendations and SOP.

(2) **FDA-unlicensed Reagents.** For FDA-unlicensed reagents:

(a) Testing is performed to document that the reagent meets or exceeds FDA standards for sensitivity and specificity before the reagent is placed in service.

(b) Quality control testing is performed each day of use.

e. **Proficiency Testing.** The (insert facility name) blood bank or transfusion service participates in a Proficiency Testing Program in order to compare its testing results with those of a peer group of blood bank or transfusion service of comparable complexity.

(1) The facility is enrolled in a proficiency testing program that is appropriate for its level of testing and meets CLIA'88 and other regulatory and accreditation requirements or standards.

(a) When commercial proficiency testing is not available, an alternate method must be devised to verify accuracy.

(b) The alternate assessment must be performed at least twice per year.

(2) Proficiency testing samples are handled as routine patient and donor samples; testing is performed by bench technical staff using routine methods.

(a) Proficiency testing must be rotated among all technical personnel on all shifts.

(b) Additional testing of proficiency testing material for the purpose of education may not be performed until after the submission deadline.

(c) Inter-laboratory communication about proficiency testing is prohibited until after the deadline for submission of data.

(d) Proficiency testing samples may not be referred to another laboratory

(3) The supervisor technologist and medical director actively review and evaluate the results of proficiency testing and take appropriate corrective action steps as necessary.

(4) Documentation of the Proficiency Testing Program is maintained and includes:

(a) Dates,

(b) Observed results,

(c) ID of the individual performing the tests,

(d) Interpretation,

(e) Supervisory and/or medical director review, and

(f) Corrective actions, if any. Corrective action must be initiated within 30 days of the receipt of the evaluation report.

g. **Label Control.** All labels in use are selected to meet all criteria specified in regulatory requirements and accreditation standards. *NOTE: Choose one of the two options (subpars. 6g(1) or 8g(2)) following or modify as appropriate for the specific facility.*

(1) The (insert facility name) Transfusion Service maintains a label control system: to ensure that each shipment of labels (of each type in use) meets pre-determined specifications and to detect and track any recurrent problems. The facility maintains a master set of labels in

current use. *NOTE: The system needs to be appropriate for the scope of labeling activities, if any, e.g., labels used on pooled components or any other component which may be modified by the facility after receipt from the supplier.*

OR

(2) The (insert facility name) blood bank maintains a label control system which includes:

- (a) A method to ensure that all labels selected meet all applicable regulatory and accreditation requirements.
- (b) A defined process for receipt, inspection and testing of each batch of labels before use.
- (c) Maintenance of a master set of labels in current use.
- (d) A process to capture and document recurrent label problems.
- (e) A process to detect and track duplicate labels.

h. **Monitoring and Control of Blood Component Production Processes.** The facility must define product specifications based on FDA regulations and all relevant accreditation standards and incorporate these into the SOP manual.

(1) The SOP manual details how to identify and handle components not meeting these specifications.

(2) The facility has defined criteria and procedures for release of all finished blood components.

(3) Lot numbers for all materials used by the transfusion center in the collection, processing, or dispensing of blood or blood products must be documented.

*NOTE: All types of blood components produced by or modified by the facility need to be included in the program. This part of the SOP manual needs to be expanded, modified, or omitted depending on the scope of operations of the facility.*

i. **Handling, Storage, Distribution, and Transport**

(1) The defined storage conditions in place for each component must meet all regulatory requirements and accreditation standards, and are to be specified in the corresponding SOP. Storage equipment calibration, quality control procedures, and preventive maintenance ensure these defined conditions are maintained.

(2) The facility uses a system for shipping and transportation of components which ensures that an appropriate temperature range is maintained for each component.

(3) The facility has a defined system for tracking the history and final disposition of all blood components it handles.

(4) The facility disposes of any blood component which does not meet the defined criteria for issue. A record is maintained of all disposals, including the date and time of disposal, the type of disposition, and the identity of the person performing each action.

j. **Computer Systems.** The facility uses a computer system designed to provide additional control over its critical processes. The computer system (hardware and software) is validated at the time of installation and appropriately maintained to ensure that it functions according to predetermined specifications. This validation consists of:

(1) Information Resources Management Service and the VA blood bank or transfusion service software developers work together in the development and implementation of appropriate hardware and software “user acceptance.” The blood bank or transfusion service works in conjunction with the validation protocols, which follow FDA and VA regulations and guidelines.

(2) New hardware is validated at the time of installation and after any significant modification or change.

(3) New versions of software and changes (“patches”) are validated.

(4) Validation results are reviewed by the responsible individual, or designee, before implementation of the software.

(5) A defined backup system is followed for computer downtime.

k. **Maintaining an inventory of Critical Supplies**

(1) There is a defined inventory process to ensure adequate critical supplies.

(2) Lots numbers of all materials used by the transfusion center in the collection, processing, or dispensing of blood or blood products must be documented.

l. **Other Mechanisms of Process Control.** The facility uses additional mechanisms, as appropriate to the specific task, to provide on-going assurance that procedures are consistently producing the expected results. These include:

(1) Real-time self-assessments of selected processes.

(2) Periodic internal audits of overall operations.

(3) Statistical process control measures.

## 7. DOCUMENTS AND RECORDS MANAGEMENT

a. **Document Control.** The facility maintains a system of document control which includes the following:

- (1) Requirement for uniform format for all SOPs and forms.
- (2) Defined process for approval and issue of policies, procedures, and forms.
- (3) Defined process for revisions, changes, or modifications to policies, procedures, and forms.
- (4) System for archiving, retention, and retrieval of inactive policies, procedures, and forms.

b. **Record Keeping.** The facility maintains a system for generation, retention, storage and retrieval of all records related to the blood bank or transfusion service, which specifies the following:

- (1) Records are completed according to instructions in the relevant SOP.
- (2) Records are retained for the required period as defined by the most stringent requirements of VA, FDA, and the accrediting agency.
- (3) Records are stored in a manner which maintains their integrity and which permits their retrieval within a reasonable time-frame as defined by the most stringent requirements of VA, FDA, and the accrediting agency.

c. **Record Review.** Each facility must ensure that records are reviewed in a manner and on a schedule which meets the most stringent requirements of VA, FDA, and the accrediting agency.

## 8. INCIDENTS, ERRORS, ACCIDENTS; NONCONFORMITIES; AND COMPLICATIONS

The (insert facility name) blood bank or transfusion service develops and maintains a system designed to detect and analyze all incidents, accidents, and errors which have the potential to impact on the quality and/or safety of products or services provided. ***NOTE: This program's goal is continuous quality improvement.***

### a. **Identification and Reporting**

- (1) Staff is encouraged to report incidents, errors, and accidents through a non-punitive system.
- (2) Activities within the laboratory, as well as transfusion-related activities which take place elsewhere within the medical center (or other appropriate term), are monitored.

b. **Classification of Incidents, Errors, and Accidents.** The facility has a defined process for documentation of each incident, error, or accident and for the classification or categorization of each event on the following bases:

(1) Severity, i.e., the degree of impact on product or service quality and the potential to cause an adverse effect in the patient or recipient.

(2) Reportable versus non-reportable.

(3) Re-occurring or not.

c. **Evaluation, Response, and Corrective Action**

(1) The facility has a defined process for immediate follow-up of each incident, error, and accident which ensures the following:

(a) Notification to FDA of transfusion-related fatalities within required time limits.

(b) Notification to FDA of reportable accidents or errors related to blood components or medical devices.

(c) Biological Product Deviation Reporting (BPDR) to FDA in accordance with 21 CFR 606.171.

(d) Notification to the blood supplier of adverse recipient reactions that may require immediate action by the supplier (e.g., Transfusion-related Acute Lung Injury (TRALI) reaction which may be attributed to donor leukocyte antibodies).

(e) Patient or recipient follow-up to rule out adverse effects, when appropriate.

(f) Notification to the clinical team of immediate and delayed hemolytic transfusion reactions.

(2) The incident, error, or accident is evaluated promptly to identify the root cause and determine the need for a systems change or staff retraining. *NOTE: The aim is to prevent recurrence of the problem.*

(3) Each incident, error, or accident is reviewed by the blood bank transfusion service supervisory technologist and the medical director.

(4) Corrective actions are monitored for effectiveness.

d. **Documentation.** Complete documentation is maintained for each incident, error, or accident.

e. **Analysis and Trending.** Periodic review and analysis of incidents, accidents, or errors is performed by the blood bank or transfusion service in cooperation with the “Quality Unit” to detect patterns or trends and to define areas in need of process improvement.

f. **Lookback and Post-transfusion Infections**

(1) The facility has a defined process for handling “lookbacks” as required by VA and FDA regulations.

(2) When a patient receives unsuitable blood or blood products, the patient’s provider is responsible for notifying the patient. If the clinician is unwilling to notify the patient, the ultimate responsibility rests with the blood bank or transfusion service.

(3) The facility has a defined process for notifying the blood bank or transfusion service of cases of suspected transfusion-transmitted disease, and has a standard method of reporting this information to the blood supplier.

**9. ASSESSMENT**

a. **Internal Assessment**

(1) **Operational Self-Assessment and/or Systems Checks.** The (insert facility name) blood bank or transfusion service is actively involved in performing real-time internal assessments on an on-going basis. Over time all critical functions are encompassed in these assessments, but a specific area may be targeted at a given time based on indicators suggesting that a particular process may be out of control.

(a) The following major systems are assessed: **NOTE:** *Choose those which apply from the following suggested list.*

1. Assessed by all facilities:

a. Storage, distribution, and dispensing;

b. Confirmatory donor testing;

c. Recipient testing and compatibility testing;

d. Blood administration;

e. Investigation of adverse effects; and

f. Information management.

2. Assessed by blood collecting facilities only:

- a. Donor suitability,
  - b. Blood collection,
  - c. Component processing,
  - d. Donor testing, and
  - e. Test result review and labeling.
3. Assessed only if process performed at the facility in question:

- a. Autologous transfusion (pre-operation, during the operation, post-operation);
- b. Apheresis (therapeutic, donor);
- c. Tissue storage and dispensing;
- d. Histocompatibility testing and organ transplantation; and
- e. Hematopoietic progenitor cells.

(b) A system for data capture must be developed before beginning each systems check.

(2) **Quality Indicators.** The facility defines quality indicators for selected activities as a method of on-going monitoring.

(3) **Internal Audits**

(a) Comprehensive internal audits are performed in a standardized manner by (insert facility name) blood bank or transfusion service at least annually. These audits are designed to:

- 1. Ensure operational activities meet pre-determined standards.
- 2. Determine the effectiveness of the current quality program, and identify targets for program improvement.
- 3. Identify areas for process improvement.

(b) These audits are performed by (an) individual(s) who is (are) not directly responsible for the process being audited. **NOTE:** *Where possible the "Quality Unit" is actively involved.*

(4) **Corrective Action and Follow-up.** Based on the results of the systems checks and internal audits, the blood bank or transfusion service supervisor or medical director works with

the "Quality Unit" in identifying problems, formulating appropriate corrective actions, and monitoring the effectiveness of any actions taken.

(5) **Tracking and Trending.** The blood bank or transfusion service supervisor or medical director works with the "Quality Unit" in analyzing results of current assessments and comparing them to previous findings. Any trends identified help in prioritizing areas for process improvement.

(6) **Reporting.** The blood bank or transfusion service works with the "Quality Unit" in compiling and reviewing the results of these systems checks and internal audits. Reports are prepared detailing the findings, any problems identified, and any corrective actions taken. The reports are then forwarded, for review, to the Pathology and Laboratory Medicine Service Chief, or designee, and to the \_\_\_(medical center multidisciplinary committee (or insert another term))\_\_\_ which has oversight of transfusion practices.

b. **External Assessment.** The  (insert facility name)  blood bank or transfusion service undergoes periodic external assessments which are either required by regulation or invited on a voluntary basis by the facility. The feedback obtained is analyzed by the supervisory technologist and medical director of the blood bank or transfusion service and the Quality Unit with a goal of continuous quality improvement.

(1) **Informal Assessments by Other Institutions** (Include if desired). The facility periodically may invite a qualified individual, from an outside institution with an operation of comparable size and scope, to evaluate a specific transfusion-related process.

(2) **Formal Assessments.** The  (insert facility name)  blood bank or transfusion service is assessed on a scheduled basis by the following regulatory or accrediting agencies:

*NOTE: Modify list as appropriate.*

(a) FDA.

(b) CAP.

(c) The Joint Commission.

(d) AABB.

c. **Analysis of External Inspection Results.** The facility has a process for evaluating and comparing results of external assessments by different groups, and then looking for any trends which might point to areas to prioritize for process improvement.

## 10. PROCESS IMPROVEMENT THROUGH CORRECTIVE AND PREVENTATIVE ACTION

a. The  (insert facility name)  blood bank or transfusion service has a system in place to facilitate process improvement. These efforts are supported by Pathology and Laboratory

Medicine Service and medical center management who are committed to the concept of Continuous Quality Improvement and to the training and involvement of all staff in this process.

- b. The need for process improvement is identified in several ways:
  - (1) Systems checks;
  - (2) Internal audits;
  - (3) Quality Indicators;
  - (4) External assessments (FDA, The Joint Commission , CAP, AABB);
  - (5) Incidents, errors, or accidents;
  - (6) Customer complaints; and
  - (7) Perceived opportunity for improvement in quality or efficiency.
- c. The facility has a defined approach to process improvement; this approach encompasses:
  - (1) Prioritization of problems to be solved,
  - (2) Collection of baseline data,
  - (3) Brainstorming on possible solutions,
  - (4) Selection of solution,
  - (5) Development of implementation program,
  - (6) Execution of plan, and
  - (7) Monitoring impact and effectiveness in solving problems.

## 11. FACILITIES AND SAFETY

a. **Facilities.** The (insert facility name) blood bank or transfusion service maintains, within the limits of \_\_\_(the medical center's (or more appropriate term))\_\_\_ space and budgetary limitations, a space conducive to the efficient provision of safe and high quality blood components and services.

b. **Safety.** The (insert facility name) blood bank or transfusion service adheres to the medical center and Pathology and Laboratory Medicine Service policies and procedures. These policies and procedures meet the requirements of the Occupational Safety and Health

Administration, FDA, and (list other regulating agencies as appropriate). These policies address the following general concerns:

- (1) Fire protection and control.
- (2) Electrical safety.
- (3) Standards for handling of hazardous materials (e.g., chemicals, carcinogens, poisons, compressed gases, etc.).
- (4) Infection control.
- (5) Waste disposal.
- (6) Injury and accident management.
- (7) Security.

**PROTOCOL FOR SECOND REVIEW OF SURGICAL PATHOLOGY CASES**

1. A second review must be performed on 100 percent of malignancies (excluding skin squamous and basal cell carcinomas).
2. Ten percent of the total annual surgical pathology examinations must be reviewed. The cases are to be divided into the following categories:
  - a. Lung and lower respiratory tract.
  - b. Lower gastrointestinal tract (colon, rectum, anus).
  - c. Prostate and genitourinary system.
  - d. Upper gastrointestinal tract (esophagus, stomach, exocrine pancreas, liver, gall bladder).
  - e. Hematopoietic system, including lymph nodes, spleen, and bone marrow.
  - f. Upper respiratory tract, head, and neck.
  - g. Endocrine system.
  - h. Skin, adnexal glands and breast.
  - i. Central nervous system.
  - j. Renal system.

***NOTE:** Some Department of Veterans Affairs (VA) medical centers may lack a sufficient number of cases representative of the systems noted. In these circumstances, the objective is to re-review a percentage of cases from the organ categories that constitute the majority of the laboratory's caseload.*

**3. Examples**

a. Example 1. If pulmonary pathology specimens constitute 40 percent of a laboratory's workload per year, then the volume of cases selected for re-reviews must reflect this percentage. The Chief or Director, Pathology and Laboratory Medicine Service, is responsible for ensuring that adequate percentages are chosen from each organ system for re-review.

b. Example 2. If a Laboratory Service performs 2,000 cytology cases a year, then the 200 cases chosen for re-review must be divided between the organ systems listed, insofar as is possible. If the number of cytology cases is lacking in a given organ system, then cases from other organ systems may be substituted to reach the required 10 percent.

**SAMPLE OF A FORMAT FOR A  
POST-MORTEM QUALITY ASSURANCE SURVEY  
(To be completed jointly by pathologist and clinician)**

This document (or information contained herein) is deemed **CONFIDENTIAL AND PRIVILEGED** under provisions of Title 38 United States Code 5705. This material must not be transmitted to anyone without proper consent or other authorization as provided by law or regulation.

Patient's Name. \_\_\_\_\_ Service. \_\_\_\_\_

Social Security Number. \_\_\_\_\_ Date. \_\_\_\_\_

Department of Veterans Affairs (VA) Medical Center. \_\_\_\_\_

Clinician. \_\_\_\_\_ Pathologist. \_\_\_\_\_

Autopsy Number. \_\_\_\_\_

**I. Post-mortem Pathologic Diagnoses**

**II. Clinical Pre-mortem Diagnoses**

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**III. Findings Clinical Significance Of Post-Mortem**

**Comment Or Check  
Appropriate Category**

- a. Major disagreement in diagnosis. \_\_\_\_\_
- b. Major unsuspected or additional diagnosis. \_\_\_\_\_
- c. Significant clarification of differential diagnosis,  
but no major disagreement. \_\_\_\_\_
- (1) Diagnosis suspected, but not confirmed. \_\_\_\_\_
- (2) Diagnosis among two or more equally considered. \_\_\_\_\_

- d. Confirmation or verification of major diagnosis. \_\_\_\_\_
- e. Autopsy indeterminate; does not clarify or resolve major issue. \_\_\_\_\_

**IV. Clinical Factors Related to or Contributing to Cause of Death (Check where applicable)**

**Comment or Check Appropriate Category**

- a. Unremitting course of disease. \_\_\_\_\_
- b. Error in judgment or treatment plan. \_\_\_\_\_
- c. Result of complication or therapeutic procedure. \_\_\_\_\_
- d. Unrecognized diagnosis with pre-mortem evidence, which existed by:
  - (1) Physical exam. \_\_\_\_\_
  - (2) Patient complaint or symptom. \_\_\_\_\_
  - (3) Clinical course. \_\_\_\_\_
  - (4) Inattention to or misinterpretation of diagnostic tests. \_\_\_\_\_
- e. Other. \_\_\_\_\_

**V. Summary Comment**

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**GUIDELINES FOR PERFORMING POST-MORTEM EXAMINATIONS ON  
FORMER PRISONERS OF WAR (POWs)**

**1. Background**

a. A Special Registry was established in 1980 at the Armed Forces Institute of Pathology for pathological material from former Prisoners of War (POWs) of World II, the Korean Conflict and Vietnam Era.

b. Sequelae of POWs are both physical and psychiatric; however, these physical sequelae have been more prevalent in the Japanese and Korean POWs than in the European POWs. Parasitic disease, tuberculosis, cardiovascular-renal disease, gastrointestinal and liver disease, as well as neurological disorders, have all been major causes of disability.

c. Review of injuries, illnesses, and psychiatric disorders among POWs of the Vietnam Era indicates the most common physical illnesses diagnosed in Army POWs on repatriation were:

- (1) Helminthiases,
- (2) Avitaminosis,
- (3) Bacterial skin infections and dermatophytosis,
- (4) Peripheral nerve injury,
- (5) Hearing loss,
- (6) Diseases of the retina and optic nerves,
- (7) Malaria,
- (8) Amoebiasis,
- (9) Acute upper respiratory infections,
- (10) Dental problems, and
- (11) Compressed fractured vertebrae.

**2. Autopsy.** Obtaining permission for autopsy examination on former POWs is strongly encouraged. Autopsies performed on former POWs are to be in accord with the accepted autopsy protocol currently in use.

a. In addition to the routine autopsy procedures, a morphologic study needs to be made of tissue samples from:

- (1) Peripheral nerves, including sections of skeletal muscles with dorsal root ganglia;
- (2) Spinal cord at several levels including cervical widening;
- (3) Medulla at the level of the hypoglossal nucleus;
- (4) Midbrain;
- (5) Hypothalamus, including mammillary bodies and wall of third ventricle;
- (6) Thalamus;
- (7) Hippocampus;
- (8) Optic nerves; and
- (9) Cortex from each cerebral lobe.

b. Sections from the nervous system need to be stained for myelin and axons in addition to the hematoxylin and eosin stains.

c. Further recommendations include taking specimens from the testes, prostate, bladder, and kidney.

(1) Half of each testis needs to be fixed.

(2) Material from the prostate needs to include the capsule and the urethra.

(3) Sections from the bladder need to include any obvious lesions. If none, sample needs to include the trigone.

(4) Sections from the kidney need to include cortex and pelvis.

d. Most importantly, attention needs to be directed toward the search for and identification of diseases and disorders not expected in the autopsy of a non-military patient.

*NOTE: Familiarity with the spectrum of diseases likely to affect former POWs enables the pathologist to render a more complete medical assessment of patients in this select group.*

3. All pathological material (surgical, cytologic, and autopsy) from POWs must be examined and reported in the customary manner at each medical center. A duplicate set of slides, blocks, and representative wet tissue is to be forwarded to the Armed Forces Institute of Pathology.

a. All material for shipment to Armed Forces Institute of Pathology must be packaged in the usual manner and addressed to: Director, Armed Forces Institute of Pathology, "Attention Former POW Registry."

b. The packaged specimens must be further identified by affixing VA Form 10-5558, POW Label. This label measures 2 1/2 by 5/8 inches and has the letters POW in green on a white background.



**SCHEDULE FOR EXAMINATION OF SYSTEMATIC EXTERNAL REVIEW  
OF SURGICAL (SERS) CASES AT THE ARMED FORCES INSTITUTE  
OF PATHOLOGY**

**JANUARY**

Gastrointestinal  
Pulmonary  
Dermatopathology

**MARCH**

Genitourinary  
Hematologic  
Hepatic

**MAY**

Gastrointestinal  
Pulmonary  
Dermatopathology

**JULY**

Genitourinary  
Hematologic  
Hepatic

**SEPTEMBER**

Gastrointestinal  
Pulmonary  
Dermatopathology

**NOVEMBER**

Genitourinary  
Hematologic  
Hepatic