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M-2, Part VI
Chapter 6

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1. Transmitted is a complete revision to Department of Veterans Affairs, Veterans Health Administration Manual M-2, "Clinical Programs," Part VI, "Pathology and Laboratory Medicine Service," Chapter 6, "Surgical Pathology, Cytopathology and Electron Microscopy," formerly entitled "Standardization of Serologic Testing for Syphilis in Clinical Laboratories of the Veterans Administration."

2. Principal changes are:

a. Paragraph 6.01: Describes the purpose of the chapter;

b. Paragraph 6.02: Establishes general policy for surgical and cytopathology services, and electron microscopy in VA medical centers;

c. Paragraph 6.03: Delineates the responsibilities of the Chief, Pathology and Laboratory Medicine Service;

d. Paragraph 6.04: Describes the requirements of evaluating specimens and reports;

e. Paragraph 6.05: Proscribes the elements of continuous quality improvement;

f. Paragraph 6.06: Provides requirements for proficiency testing;

g. Paragraph 6.07: Establishes requirements for accessing and examination of specimens;

h. Paragraph 6.08: Describes requirements for reporting and storage of specimen slides;

i. Paragraph 6.09: Establishes criteria for data processing;

j. Paragraph 6.10: Describes the structure of VA Electron Microscopy (EM) Programs;

k. Paragraph 6.11: Describes requirements for operations in EM units; and

l. Paragraph 6.12: Describes the use of immunocytochemistry functions.

3. Filing Instructions

Remove pages	Insert pages
23 through 24	6-i through 6-ii
	6-1 through 6-20
	6A-1 through 6A-2

4. RESCISSIONS: M-2, Part VI, Chapter 6, change 67, dated July 23, 1985, and VHA Circular/Directives: 10-64-005, 10-78-212, 10-78-222, 10-78-235, 10-79-241, 10-79-252, 10-79-258, 10-80-254, 10-80-270, 10-81-209, 10-82-237, and 10-83-198.

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CONTENTS

CHAPTER 6. SURGICAL PATHOLOGY, CYTOPATHOLOGY AND ELECTRON MICROSCOPY

PARAGRAPH PAGE

6.01 Purpose 6-1

6.02 Policy 6-1

6.03 Responsibilities of Chief, Pathology and Laboratory Medicine Service 6-2

6.04 Evaluation of Anatomic Pathology Specimens 6-2

6.05 CQI (Continuous Quality Improvement) 6-3

6.06 Proficiency Testing in Anatomic Pathology 6-5

6.07 Accessing and Examination of Specimens 6-6

6.08 Internal Quality Control System-Mandated Second Review of Cases 6-8

6.09 Anatomic Pathology Reporting and Specimen and/or Slide Storage 6-10

6.10 Data Processing for Anatomic Pathology 6-12

6.11 Diagnostic Electron Microscopy 6-13

6.12 Operation of Diagnostic Electron Microscopy Units 6-15

6.13 Immunocytochemistry 6-20

APPENDIX

6A Protocol for Second Review of Surgical Pathology Cases 6A-1

RESCISSIONS

The following material is rescinded:

1. Manuals

M-2, Part VI, Chapter 6, change 67, dated July 23, 1985.

2. Circulars/Directives

10-64-005
10-78-212
10-78-222
10-78-235
10-79-241
10-79-252
10-79-258
10-80-254
10-80-270
10-81-209
10-82-237
10-83-198

CHAPTER 6. SURGICAL PATHOLOGY, CYTOPATHOLOGY AND ELECTRON MICROSCOPY

6.01 PURPOSE

The purpose of this chapter is to provide direction and guidance to Department of Veterans Affairs (VA) medical facilities regarding surgical pathology, cytopathology, and diagnostic electron microscopy.

6.02 GENERAL POLICY

a. Anatomic Pathology. The subspeciality of anatomic pathology includes surgical pathology, cytopathology, and diagnostic electron microscopy. Diagnostic services in anatomic pathology must provide regular, conveniently available, accurate and clinically useful descriptive, evaluative and complete diagnoses for all anatomic specimens obtained in the VA medical center and its outreach functions.

(1) Standards for anatomic pathology in the Veterans Health Administration (VHA) will be in accordance with those published in the current edition of the Accreditation Manual for Hospitals by Joint Commission on Accreditation of Healthcare Organizations (JCAHO), and those of the College of American Pathologists (CAP) Commission on Laboratory Accreditation.

NOTE: Current accreditation by JCAHO and CAP is required for all VA medical centers providing anatomic pathology services.

(2) Each VA medical center which provides anatomic pathology services must have areas properly designed, equipped and maintained to provide current standards of function and safety for those services offered; this includes, but is not limited to: receiving, processing, staining, examination, and storage of tissue specimens.

(3) All equipment used in connection with these services will be properly maintained according to manufacturer's and accrediting bodies' standards.

b. Surgical Pathology. VA medical centers shall provide surgical pathology services if tissue specimens are obtained from outpatients, or inpatients. If a surgical pathology service is provided it will include frozen as well as routine sectioning, and special staining including immunohistochemistry.

(1) Only qualified, licensed pathologists certified by an American board of pathology will provide the written report for surgical pathology examinations.

(2) Pathology and Laboratory Medicine Service in VA Central Office will arrange for an approved proficiency program for ongoing proficiency testing in surgical pathology.

c. Cytopathology. If cytology specimens are obtained, cytopathology services will be provided. If cytopathology services are provided, standard methods for processing all types of cytology specimens will be available.

(1) All cytology specimens obtained at the VA medical center (both outpatient and inpatient) will be sent to the Pathology and Laboratory Medicine Service for evaluation and diagnosis by a qualified pathologist.

(2) All screening of VA cytopathology slides must be performed in the laboratory of the medical center providing the service. Exceptions to this policy must be approved in writing by the Chief of Staff.

(3) Only qualified, licensed pathologists certified by an American board of pathology will provide the written report for surgical pathology examinations.

(4) No person who screens cytopathology slides may screen more than 80 slides per 24 hour period, including any screening outside of the VA medical center. All persons in Pathology and Laboratory Medicine Service who screen cytopathology slides must meet the qualifications in Chapter 12.

(5) Pathology and Laboratory Medicine Service in VA Central Office will arrange for an approved national proficiency program for ongoing proficiency testing in cytopathology in each VA medical center that performs cytopathology.

d. Electron Microscopy. Diagnostic electron microscopy services will be provided regionally at VA facilities selected by VA Central Office.

6.03 RESPONSIBILITIES OF THE CHIEF, PATHOLOGY AND LABORATORY MEDICINE SERVICE

a. The Chief, Pathology and Laboratory Medicine Service, is responsible for:

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

(2) Ensuring certification, documentation of all credentials, and performance of the professional medical and technical staff under the chiefs jurisdiction.

(3) Ensuring that no activity is performed by an individual who lacks the education, training, and experience required for that activity (see Ch. 12).

b. The Chief, Pathology and Laboratory Medicine Service, may designate a pathologist as Chief, Anatomic Pathology Section, who acts as supervisor over the operations of each specialty area of anatomic pathology. This individual must have sufficient experience in the field of anatomic pathology and be certified by an American Board of Pathology.

6.04 EVALUATION OF ANATOMIC PATHOLOGY SPECIMENS

a. 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 center and their diagnoses will be available to aid in interpretation of the current specimen.

(1) Relevant clinical history, and if possible, relevant anatomic pathology specimen preparations from other health care providers, will be obtained and reviewed prior to final evaluation.

(2) Consultations and review of pertinent VA patient material previously obtained from other health care providers will also be available.

b. All current anatomic pathology reports will be documented in the VA medical center's Decentralized Hospital Computer Program (DHCP). This includes those reports

on VA patient specimens evaluated through contract, fee basis, sharing agreements, or at other VA medical centers.

c. If VA anatomic pathology specimens are evaluated at a non-VA facility, that laboratory must be accredited by CAP and have a Certificate of Accreditation issued by the Department of Health and Human Services (HHS) under the provisions of the Clinical Laboratory Improvement Amendments of 1988 (CLIA 88).

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

(2) These reports must include the name of the medical center where the evaluation was performed, as well as the pathologist at that medical center responsible for the evaluation.

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

(4) All contract pathologists will meet the qualifications found in this chapter, and will be governed by all provisions of this chapter and Chapter 1.

6.05 CONTINUOUS QUALITY IMPROVEMENT (CQI)

a. Quality improvement in anatomic pathology including surgical pathology, cytopathology and diagnostic electron microscopy focuses on mechanisms to maintain and improve the quality of care for VA patients.

(1) In quality improvement, emphasis is given to those factors shown to generate the greatest potential of risk to the patient, as well as those activities identified as most important to patient care.

(2) The programs systematically:

(a) Identify components of risk;

(b) Continually monitor selected data for levels of risk, and trends in those levels, and documents activities to improve patient care; and

(c) Reduce risk of harm or injury to patients;

(3) Each VA medical center must have a written CQI Program for the components of anatomic pathology.

(4) National programs for continuing education, data acquisition, external peer review and proficiency testing will be utilized by Pathology and Laboratory Medicine Service, VA Central Office, to continually assess and improve the quality of anatomic pathology services.

(5) Outcomes include improvements in both medical center and individual care providers (see Ch. 14).

b. Each Chief, Pathology and Laboratory Medicine Service, must develop and implement a CQI Program using the standards delineated in this chapter. NOTE: All aspects of anatomic pathology service provided at that VA medical center will be included in the program. The CQI Program will:

(1) Include, as a key component, the correlation of diagnoses from each of the various anatomic pathology subsections (surgical pathology, cytopathology and diagnostic electron microscopy). NOTE: If an autopsy was performed, the findings (see Ch. 9) will be correlated with all anatomic pathology material obtained from that patient.

(2) Generate a report which will be reviewed in Pathology and Laboratory Medicine Service's monthly meetings. NOTE: Quarterly and annual reports should be generated to review trends.

(3) Be part of each VA medical center's Quality Improvement Program operations.

c. Included in the local VA medical center's CQI plan will be mandatory external Quality Improvement Programs.

(1) These programs are arranged and monitored by the Director, Pathology and Laboratory Medicine Service, VA Central Office, and include, but are not limited to the following:

(a) The Armed Forces Institute of Pathology (AFIP) Histopathology Quality Assessment Program,

(b) The AFIP Systematic External Review of Surgicals (SERS), and

(c) The American Society of Clinical Pathologists (ASCP) CheckPath Program in cytopathology.

NOTE: Other similar programs may be included at the discretion of each Chief, Pathology and Laboratory Medicine Service.

(2) Some of these programs document medical center performance, while in surgical pathology and cytopathology others will be person-specific, as required by CLIA 88.

(3) In all cases, individual performance appraisal will be ensured by the Chief, Pathology, and Laboratory Medicine Service, in accordance with established VA policy in MP-5, Part I, Chapter 430, "Performance Management System."

d. Periodically, VA Central Office Pathology and Laboratory Medicine Service, will issue a memorandum containing proposed monitors for CQI.

(1) Some will be mandated for inclusion in each local CQI. Others will be suggestions.

(2) The list of monitors:

(a) Will reflect results of an ongoing assessment of activities which have proven significant impact on patient care;

(b) Are refined from previous memoranda; and/or

(c) Have been raised as important monitors by other VA Central Office Services, or national organizations, concerned with health care which have relevance to patient care of veterans.

6.06 PROFICIENCY TESTING IN ANATOMIC PATHOLOGY

a. Proficiency tests are intended to identify laboratories and individuals who are unable to reliably distinguish clinically important findings and report them in a conventional manner so as to communicate the important finding(s) to the patient's physician.

b. Proficiency testing will include all activities of anatomic pathology service provided at each VA medical center and by each individual responsible for reporting anatomic pathology material at that medical center.

(1) Testing will:

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

1. Having identified deficiencies, testing will lead to focused, additional education and training to remedy the deficiency.

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

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

4. This testing will not be used to evaluate degrees of expertise.

NOTE: Testing itself will not be considered a teaching mechanism nor a form of continuing education.

(b) Adhere to principles established by recognized authorities on the inherent limitations of the administrative process.

(c) Determine proficiency of the specific activities performed at a VA medical center and by an individual. If the activity is diagnostic, testing should identify inability to recognize and distinguish clinically important diagnostic categories, or abnormalities.

(d) Meet standards for proficiency testing.

(1) In so far as possible the test slide(s) will be evaluated in the routine manner for patient specimens from that VA medical center.

(2) If the individual being tested judges that consultation would be included in the routine evaluation of specific material, such consultations are permitted; however, it must be indicated on the test answer that consultation was obtained (even if the consultation did not alter the individual's evaluation).

(3) Proficiency will be judged only after analysis of significant numbers of test answers are obtained from each individual test slide.

(2) Testing material will:

(a) Reflect the case mix, patient demographics, and disease profiles of the patients in the VA health care system. Only actual case material in the form of glass slides processed according to standard practice, with verified clinical information, and follow-up will be utilized as test material.

(b) Be reviewed by a panel of pathologists with recognized expertise with the specific specimens.

c. Pathology and Laboratory Medicine Service in VA Central Office will:

(1) Arrange for an approved proficiency program for ongoing proficiency testing in surgical pathology and cytopathology.

(2) Provide proficiency review of the Diagnostic Electron Microscopy Programs in Pathology and Laboratory Medicine Service as specified.

(3) Administer the testing programs. Reports of medical center and individual performance will be submitted quarterly to the Chief, Pathology and Laboratory Medicine Service, at each VA medical center providing anatomic pathology service.

(4) Oversee the activities of each VA medical center's anatomic pathology service. If indicated, focus reviews will be conducted and action implemented to ensure that each Pathology and Laboratory Medicine Service continues to provide high standards of service and patient care.

d. The Chief, 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. The VA performance management System (MP-5, Pt. I, Ch. 430) provides guidance in this area as it relates to managing the performance appraisal processes and providing assistance to improve noted performance deficiencies. NOTE: However, education and training needs of employees should be monitored on an on-going basis to ensure the staff is adequately prepared and trained to perform their assigned duties.

6.07 ACCESSING AND EXAMINATION OF SPECIMENS

a. All specimens removed during surgical procedures must be sent to Pathology and Laboratory Medicine Service for evaluation by a qualified pathologist. Cytology specimens obtained at the VA medical center (both outpatient and inpatient) will be sent to the Pathology and Laboratory Medicine Service for evaluation and diagnosis by a qualified pathologist.

(1) All specimens must be properly identified at the time of the procedure, and must be accompanied by a requisition form. The information on the requisition form must be legible and include:

(a) Full identification of the patient,

(b) Identity of the patient's physician,

(c) Identity of the submitting physician,

(d) Type and source of the specimen (organ/tissue),

(e) Date when the specimen was obtained,

(f) Pertinent clinical information including specific reasons the specimen was obtained, and

(g) Clinically suspected abnormality.

(2) On receipt of the specimen, Pathology and Laboratory Medicine Service will assign a unique accession number which will be recorded on all material associated with that specimen throughout processing, evaluation and storage.

(3) If the specimen or specimen material is sent to another VA medical center, or another laboratory, for specialized evaluation or consultation, the unique accession number and patient identification must be recorded on all of the material. Any subsequent identifying information must be recorded and transmitted when the evaluation returned to Pathology and Laboratory Medicine Service.

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

b. 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 written approval of the VA medical center's Clinical Executive Committee; and the laboratory preforming the examination must meet the accreditation standards of JCAHO and CAP.

c. Whenever special procedures are utilized in evaluating specimen material, appropriate control material(s) will be processed concurrently to validate the procedure.

d. Only qualified, licensed pathologists certified by an American board of pathology will provide the written report for anatomic pathologic examinations.

e. Any person examining cytopathology preparations must be qualified to perform that specific activity (see Ch. 12).

f. Only qualified, licensed pathologists certified by an American Board of Pathology will provide the written report for surgical pathology examinations.

g. The Chief, Pathology and Laboratory Medicine Service, is responsible for ensuring that:

(1) All pathologists performing anatomic pathology evaluations seek consultation for all cases where doubt exists concerning the diagnosis.

(2) Consultations are obtained for uncommon lesions and lesions unfamiliar to the pathologist.

(3) A pathologist will be available for consultation when requested by a clinical physician.

(4) A pathologist will be available to provide oral interpretation of frozen section evaluations of surgical specimens which require evaluation during the surgical procedure.

h. If the evaluation of any anatomic pathology specimen concludes that there is malignancy, and there has been no prior definitive diagnosis of that malignancy, the patient's physician must be personally, i.e., by verbal or oral communication not by

electronic or computer mail, notified within 1 working day of the time that diagnosis was made. This communication must be documented in writing by the pathologist who notifies the patient's physician.

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

(2) At those VA medical centers with only one pathologist, the second review must be obtained within a reasonable period of time after the issuance of the report. The identity of second review pathologists will be included in the report.

(3) If a patient's specimen has malignancy and there have been previous reports of malignancy from that patient, all such prior anatomic pathology reports (and when appropriate, the actual slides) will be reviewed before reaching a final evaluation of the current specimen.

6.08 INTERNAL QUALITY CONTROL - MANDATED SECOND REVIEW OF CASES

a. The Chief, Pathology and Laboratory Medicine Service, will ensure:

(1) One hundred percent second review of the diagnosis on all categories of surgical pathology cases as noted in Appendix 6A; and

(2) A second review of surgical and cytology diagnosis is performed, on no less than a quarterly basis, for at least 10 percent of all surgical pathology cases (or 300 cases, whichever is the lesser amount), and 10 percent of all cytology cases diagnosed in that medical center (see protocol described in App. 6A).

(a) Each case selected for second review by the procedures described will be recorded in a dated log book with notation as to agreement or disagreement between reviewers, and actions taken. The names of the reviewers will be signed next to the final diagnosis. All clinically significant discrepancies in diagnosis will be brought to the attention of the Chief, Pathology and Laboratory Medicine Service, and the Chairperson of the Tissue Committee. Any changes in documented diagnosis will be placed in the patient's medical record, and the patient's attending physician will be notified immediately. NOTE: Remedial action will be documented in a dated log book, and in accordance with subparagraph b.

(b) The mechanism for selecting cases for review shall ensure representation of those specimens most likely to pose diagnostic problems in VA medical center patients, e.g., tumors, borderline or controversial lesions, or cases where the diagnosis may affect the patient's ultimate treatment.

(c) Frozen sections will be reviewed at the time of surgery in cases where there may be difficulties, such as skin lesions, or organs for margins, e.g., to confirm the presence of nerve cells in a vagotomy specimen. All frozen section diagnoses that do not agree with the diagnosis on permanent section will be reviewed and the differences resolved and documented in accordance with subparagraph b.

(d) In VA medical centers with two or more pathologists, reviews should be arranged within the staff and the reviewing pathologist should initial and date the surgical

pathology report, when in is in concurrence with the diagnosis. In cases where there is disagreement, a third opinion should be obtained expeditiously either from local consultants as pathologists at an affiliated medical school, or from AFIP with a request for consultation. Once the correct diagnosis is established, it will be entered in the laboratory record and in the patient's medical record. If there is a significant change in diagnosis that affects the patient's treatment, the Chief, Pathology and Laboratory Medicine Service, will advise the Chief of Staff, and the patient's physician, or an appropriate clinical staff physician who will take action to contact the patient and revise and/or amend the treatment.

(e) In VA medical centers with only one pathologist, a documented, signed second opinion will be obtained promptly on malignant neoplasms as listed in Appendix 6A, and on at least 10 percent of all surgical pathology accessions including 50 percent of all cases with needle aspirations. In cases where long distances between medical centers, inclement weather or logistical problems preclude review within 48 to 72 hours, the second review will be performed as soon as possible, preferably no more than 7 to 10 days from the first diagnosis. The second opinion will be obtained through one or a combination of the following

1. Local consultants;

2. Another VA medical center with two or more pathologists on its staff; and/or

3. AFIP as a "rush" consultation. NOTE: The AFIP should not be consulted on all cases.

NOTE: If funding for consultation services becomes a problem, contact the Director, Pathology and Laboratory Medicine Service, VA Central Office for assistance in locating a suitable peer review laboratory.

(f) In VA medical centers with no permanent pathologist, the Chief of Staff will ensure 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, including 50 percent of all cases with fine needle aspiration, is also mandated for contract, fee-basis, or sharing agreement pathologists who provide surgical pathology, or cytology diagnostic services for VA medical centers. Dated log books and documentation of second reviews are to be maintained in the VA medical center's Pathology and Laboratory Medicine Service.

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

b. Quality Control and /or Remedial Action

(1) Quality improvement and quality assessment procedures are designed to identify potential defects in the surgical pathology diagnostic system. Once defects are identified, it is the responsibility of the Chief, Pathology and Laboratory Medicine Service, to:

(a) Institute actions for correction including additional training of staff; and

(b) Document both the problem and the actions leading to resolution.

(2) It is the responsibility of the Chief, Pathology and Laboratory Medicine Service, to ensure that:

(a) All pathologists performing surgical pathology or cytology examinations of tissues and sells, seek consultation for all cases where doubt exists concerning:

1. The diagnosis,

2. Equivocal results, or

3. Disagreement between pathologists concerning the diagnosis.

(b) The second reviewer will either make a signed and dated note of the laboratory of the initialed report, or provide a separate report or comment for attachment to the laboratory copy of the report.

(c) The results of the second pathologist's review of slides and reports are documented on a dated log book maintained in Pathology and Laboratory Medicine Service.

(3) All pathologists performing tissue and/or cytologic examinations are professionally, morally, and ethically responsible for:

(a) Examining all previous slides and tissue reports on their assigned cases; and

(b) Comparing current histologic specimens with cytologic specimens taken from the same patient, patient past and present.

(4) The pathologist will:

(a) Notify the patient's physician of every new case of malignancy, except for basal cell carcinomas; and

(b) Record the date on the surgical pathology report that the patient's physician was notified.

NOTE: For information on the monitoring of the an Electron Microscopy Program, refer them to paragraph 6.11.

6.09 ANATOMIC PATHOLOGY REPORTING AND SPECIMEN/SLIDE STORAGE

a. Authenticated and dated reports of examination of all anatomic pathology specimens submitted to Pathology and Laboratory Medicine Service will become part of the patient's record. Written diagnostic reports will be issued expeditiously to the patient's record and to the physician who submitted the specimen. NOTE: Duplicate copies of all reports will be kept by Pathology and Laboratory Medicine Service in a readily retrievable manner.

(1) The report for all anatomic pathology specimen examinations must be on SF 515, Medical Record Anatomic Pathology, or DHCP; and it must be legible , and must include:

(a) Full patient identification;

(b) Identity of the patient's physician;

(c) Identity of the submitting physician;

(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 of the VA medical center 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.

b. All diagnoses will be descriptive, and are intended to communicate clinically relevant information using standard terminology and nomenclature.

c. Grading and specific information, when clinically important, to aid in staging will be included in the report,

d. The diagnoses for all anatomic specimens will be indexed by patient for ease of retrieval.

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

f. Surgical Pathology Report. The final Surgical Pathology Report will, in addition to the items in paragraph a, include:

(1) A description of the specimen received,

(2) The written text of any verbal reports of consultations and frozen section examination, and

(3) The time of verbal notification of a diagnosis of malignancy, and the name of the person contacted.

g. Cytopathology Report. If cytology slides are screened by someone other than the responsible pathologist, the final Cytopathology Report will also include the name of that person.

h. Modification of Final Report

(1) Once released to the medical record, any modification in the final anatomic pathology report will be clearly indicated, as well as the person responsible for the modification, and the date of the modification.

(2) The original report will be removed from the medical record and replaced by the modified report.

(3) If the modification is clinically significant the patient's physician and the submitting physician will be immediately notified of the modification and the issuance of a new report.

NOTE: Only authenticated copies of diagnostic anatomic pathology reports with the patient's name, Social Security Number, name of the VA medical center, and the name of the staff pathologist will be produced and circulated outside of Pathology and Laboratory Medicine Service.

i. Retention and disposal of Pathology and Laboratory Medicine Service's copies of anatomic pathology reports will be in accordance with all applicable federal standards.

(1) The copies will be retained for 25 years.

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

(3) Representative glass slides and electron microscopic grids from all cases will be retained for at least 25 years.

(4) Representative paraffin and plastic blocks will be retained for at least 10 years.

6.10 DATA PROCESSING FOR ANATOMIC PATHOLOGY

a. Computer systems for anatomic pathology will conform to the requirements of the CAP Commission on Laboratory Accreditation, JCAHO and VHA documented policy.

(1) The environment must be adequate for continuous operation of the computer system.

(2) Procedure manuals for the computer system must be accurate, available to users and cover all functions of the software.

(3) System security must be adequate to protect software, hardware, and access to the system by unauthorized users.

(4) There must be procedures and documentation for hardware and software maintenance.

(5) The procedures should result in the least interruption of service as possible and include backup methods when the system is unavailable for prolonged periods.

b. The following functions must be available:

(1) Specimen log-in, including:

(a) Accession number,

(b) Full patient identification,

(c) Patient demographics,

(d) Patient physician,

(e) Submitting physician,

(f) Date specimen(s) was obtained, and

(g) Date specimen was received in the laboratory.

(2) Data entry of:

(a) Patient history,

(b) Preoperative, operative and postoperative diagnoses,

(c) Gross and microscopic description, and

(d) SNOMED coding of specimens.

(3) Cumulative reports of any and all previous anatomic pathology specimens.

(4) Printing reports simulating SF 515, Medical Record Anatomic Pathology, SF 503, Medical Record Autopsy Protocol.

(5) Ability to perform ad hoc SNOMED searches of the database.

(6) On line verified pathology information to physicians.

(7) Ability to modify reports after they have been released, with an audit trail of each person modifying the reports, and the time of modification.

(8) Documentation of persons responsible for activities in anatomic pathology and the date and time of those activities.

(9) Continuous Quality Improvement data entry and retrieval.

(10) A method to validate functionality and integrity of the database.

c. There will be written methods for ongoing improvements to the system.

6.11 DIAGNOSTIC ELECTRON MICROSCOPY (EM) IN LABORATORY SERVICES

a. EM is an important element in diagnostic pathology. EM services must be provided when needed for difficult diagnostic cases, and must be available in all VA Pathology and Laboratory Medicine Services with Affiliated Residency Programs in anatomic pathology. EM services can be provided in the following ways:

(1) Establishment of a diagnostic EM Program in selected VA medical centers.

(2) Shared use of EM resources acquired primarily for research, or education purposes.

(3) Referral of material for ultrastructural study to another VA medical center with EM resources in the geographic area (for example, to one of VA's Centers of Excellence in EM).

(4) Referral of material to, or use of EM resources in, an affiliated medical center or community hospital after establishment of a formal agreement for the services (see Ch. 17).

b. Functions of a diagnostic EM Program in VA Laboratory Services include:

(1) Enhancement of morphologic diagnosis.

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

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

(4) Inclusion, where appropriate, of the EM findings in hospital teaching and conferences.

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

c. The following steps must be followed to apply for an EM Program:

(1) VA medical centers 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 Decentralized Electron Microscopy Program Chief (113), VA Medical Center, Durham, NC 27705. The application must be transmitted through the Regional Director's Office with a statement from the medical center Director expressing approval, and a testing that the proposed EM resource will not create a redundancy.

(2) Preliminary review of the application for completeness by the Decentralized Electron Microscopy Program Chief.

(3) Review and recommendations to the Director, Pathology and Laboratory Medicine Service, by the Ad Hoc Electron Microscopy Review Group on the merit of the proposal. NOTE: A site visit may be included in the analysis of the proposal by members of the review group.

(4) If an application proposes joint usage for research and/or educational purposes, the Decentralized Chief will refer the application to the Office of Research and Development, and/or the Office of Academic Affairs Services, VA Central Office, for review and recommendation.

d. Basic and recurring support of a diagnostic EM program, include, but are not limited to:

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

(2) Recurring support requires funds for personnel, supplies and a service contract. The cost of the service contract will normally be 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 (see Ch. 17).

(3) A full program should have a full-time pathologist and 2.0 Full-time Employee (FTE) technical staff.

(a) Programs approved at half level will require a 0.5 FTE pathologist and 1.0 FTE technical staff.

(b) Cost of supplies for a half-level program will usually be 50 percent of the regular level.

(4) Support for EM programs, including replacement of equipment, will be funded by the VA medical center.

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

e. A VA medical center must meet the following criteria in order to be considered for national and/or regional and/or network status as a diagnostic EM Program:

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

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

(3) An active Pathology Residency Training Program and supportive medical school affiliation in pathology.

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

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

(6) Documentation that EM needs cannot be met through existing resources in VA, or the affiliated medical center, and/or the community.

6.12 OPERATIONS OF ELECTRON DIAGNOSTIC MICROSCOPY UNITS

An approved operational EM Unit is considered a permanent addition to the VA medical center's Pathology and Laboratory Medicine Service provided the utilization/productivity and quality of EM services remains satisfactory, as judged by the VA decentralized Chief, Electron Microscopy.

a. Records and Reports

(1) Specimens transmitted for EM study will be accessed and documented appropriately.

(a) Written reports will be issued promptly on all patient specimens using DHCP, or, if not available, SF 515, and placed in the patient's record, within 10 working days after accession.

(b) The reports must include:

1. Dates of accession and of diagnosis,

2. A description of the light microscopic findings,

3. A specific diagnosis and,

4. Where appropriate, pertinent literature reference.

(c) The reports will be signed by the pathologist making the diagnosis. NOTE: Electron micrograph prints need not be distributed routinely with the reports.

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

(a) A chronologically numbered accession record giving the date each specimen is accessed;

(b) The date of diagnosis and the anatomic source of each specimen; and

(c) An indexed file of diagnostic reports correlated with electron micrographs.

(3) All records will be disposed of in accordance with VHA Records Control Schedule (RCS) 10-1, Section VIII, "Laboratory Service."

(4) Numerical data (productivity) on the EM program are reported quarterly in workload reporting data in the DHCP module for Pathology and Laboratory Medicine Service.

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

(a) The reports will be prepared by the program chief of the Electron Microscopy Unit and transmitted through the Chief of Pathology and Laboratory Medicine Service, and the medical center Director to the Regional Director.

(b) The reports must be prepared in accordance with the prescribed format furnished by the Decentralized Electron Microscopy Program Chief.

(c) The reports will be completed and dispatched by the 10th working day of October each year.

(d) RCS 10-0092 (formerly RCS 11-23) continues to apply.

(6) The Format for Linking Utilization Standards for Laboratory Service Electron Microscopes, RCS 10-0092, will be submitted with the annual report and will document only the utilization of each electron microscope in Pathology and Laboratory Medicine Service. NOTE: This report is used by VA Central Office Pathology and Laboratory Medicine Service to evaluate the utilization of all electron microscopes assigned to Pathology and Laboratory Medicine Service.

b. Monitoring

(1) Appropriate monitoring procedures for emission of radiation from each electron microscope will be established in keeping the existing VA safety policy (MP-3, Pt. III, App. 5M).

(2) The following procedures are used in monitoring:

(a) Analysis of the numerical data in the workload section of the DHCP Lab Module.

(b) Analysis of the annual report.

(c) Quality assessment by the Ad Hoc Electron Microscopy Review Group, annually and on an as needed basis.

c. Sharing resources. The shared utilization of EM resources for diagnostic, research and education purposes is encouraged to promote optimal utilization.

(1) Such arrangements which include appropriate proration of recurring costs, will be developed locally, and specified in a written Structured Joint Utilization Agreement, ensuring that first priority is given to critical diagnostic needs of VA patients.

(a) The contents of the agreements will be concurred in and the document signed by the:

1. Chief, Electron Microscopy Unit, in the Laboratory Service,

2. Chief, Laboratory Service,

3. Associate Chief of Staff (ACOS) for Research and Development,

4. ACOS for Education, and

5. Chief of Staff.

(b) Completed agreements will be forwarded for approval to the Regional Director for review and recommendation, and then to the Director, Pathology and Laboratory Medicine Service, VA Central Office, or returned to the VA medical center for revision.

(c) So that the agreements remain consonant with local needs, the medical center Director will develop a procedure to ensure that all agreements are reviewed at least annually, and, at a minimum, on each anniversary of approval by the Regional Director.

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

2. If need for substantive changes is identified, a new agreement will be prepared and forwarded to the Regional Director for referral to the Director, Pathology and Laboratory Medicine Service, VA Central Office.

(2) 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 will be billed accordingly.

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

(b) The charges for the services provided must be established so that the VA medical center recovers its full costs (see M-1, Pt. I, Ch. 15, par. 15.33 and MP-4, Pt. V, Ch. 14).

d. Quality Assessment

(1) 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. However, certain aspects of the EM Program are unique. First, numerical productivity standards (i.e., numbers and types of cases examined) are specified. Second, quality assessment is achieved through a national peer review process, in addition to local reviews.

(2) The basic productivity/utilization standard for a program funded at the full level is a minimum of 300 specimens examined annually with at least 250 of the 300 specimens examined by electron microscopy. At least 67 percent (201) of the basic 300 specimens examined per year will be patient-related material. At least 51 percent (153) of the basic 300 specimens examined per year must come from VA patients. Programs funded at the half level will be expected to examine a minimum of 150 specimens annually with no less than 125 being examined by EM. NOTE: Downward deviation is not permitted except under unusual circumstances.

(3) Assessment of the quality of EM examinations is an additional factor in monitoring performance. Quality will be assessed through review by a peer group, the Ad Hoc Electron Microscopy Review Group, of cases from each diagnostic EM program. Attention will be given to:

(a) The quality of the electron micrographs,

(b) The description of the findings in the report,

(c) The accuracy of the diagnosis, and

(d) The citation of literature references, when appropriate.

(4) Determination of satisfactory performance will depend upon meeting the productivity and/or utilization standard, and in satisfying the peer group in regard to quality.

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

(a) Annually, the Director, Pathology and Laboratory Medicine Service, will prepare letters containing an evaluation of each diagnostic EM program and concluding with the assigned rating. The letters are prepared for the signature of the Regional Director.

(b) When a program is rated as Unsatisfactory, a probationary status is assigned.

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

2. 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 and/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 medical center Director, during the grace period, may decide after consultation with the Chief of Staff, the Chief, Laboratory Service, and the program chief of the EM Units, hat 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 center Director will discuss the local decision with the Director, Pathology and Laboratory Medicine Service, before any final actions for closure are taken.

e. VA Central Office Responsibilities

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

(a) Collection and analysis of utilization data from all electron microscopies assigned to Pathology and Laboratory Medicine Service.

(b) Promotion of maximal joint utilization of electron microscopes for diagnostic purposes, and approval of Structured Joint Utilization Agreements.

(c) Recommendations on relocation of under-utilized electron microscopies.

(d) Recommendations to Regional Directors on needs for additional, or replacement, electron microscopies.

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

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

(a) The group is chaired by the VA's decentralized Chief, Electron Microscopy, and serves in an expert advisory capacity to the Director, Pathology and Laboratory Medicine.

(b) The group's primary functions are to:

1. Assess the quality of diagnostic EM.

2. Review applications for new diagnostic EM Units, and make recommendations to the Director, Pathology and Laboratory Medicine Service; and

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

(3) The Director, Pathology and Laboratory Medicine may designate particular diagnostic EM programs as Centers of Excellence if they offer special expertise and/or equipment and/or procedures to other VA medical centers.

(a) The primary goal of Centers of Excellence is to facilitate the sharing of the capabilities available in these special laboratories with other VA medical centers.

(b) These Centers of Excellence in EM will be listed in the Special Clinical Resource Center Index Update.

(c) The decentralized Chief, Electron Microscopy, will act as the principal expert in determining which centers will be chosen.

6.13 IMMUNOCYTOCHEMISTRY

a. In some laboratories immunocytochemistry 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.

b. Accordingly, the policies and procedures outlined for continuing quality assessment and improvement also apply to immunocytochemical procedures.

(1) Immunocytochemical stains must be incorporated into proficiency testing programs as appropriate for the types of cases under review.

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

PROTOCOL FOR SECOND REVIEW OF SURGICAL PATHOLOGY CASES

1. A second review will be performed on 100 percent of the following cases:

a. Soft tissue malignancies,

b. All gynecologic malignancies, and

c. All bone and muscle malignancies.

2. The 10 percent (or 300 cases) for review of surgicals will be divided into categories.

a. The categories are as follows:

(1) Lung and lower respiratory tract.

(2) Lower gastrointestinal tract (colon, rectum, anus).

(3) Prostate and genitourinary system.

(4) Upper gastrointestinal tract (esophagus, stomach, exocrine pancreas, liver, gall bladder).

(6) Hematopoietic system, including lymph nodes, spleen and bone marrow.

(7) Upper respiratory tract, head and neck.

(8) Endocrine system.

(9) Skin, adnexal glands, and breast.

(10) Central nervous system.

(11) Renal system.

b. EXAMPLE: If a Laboratory Service performs 5,000 surgical pathology examinations annually, 500 surgical pathology cases (10 percent of annual total) will be re-reviewed. The cases will be divided equally into the categories listed in paragraph a, as lung and lower respiratory tract.

NOTE: Some 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 selected from those organ categories that constitute the majority of the laboratory's caseload.

c. EXAMPLE: If pulmonary pathology specimens constitute 40 percent of a laboratory's workload per year, then the volume of cases selected for re-reviews must also reflect this percentage. The Chief, Pathology and Laboratory Medicine Service, is responsible for ensuring that adequate percentages are chosen from each organ system for re-review.

d. EXAMPLE: If a Laboratory Service performs 2,000 cytology cases a year, then the 200 cases (10 percent) chosen for re-review should be divided between the organ systems as listed, insofar as 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 as described for selection of cases from surgical pathology.