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1. Transmitted is a revision to Department of Veterans Affairs, Veterans Health Administration Manual M-2, "Clinical Programs" Part VI, "Pathology and Laboratory Medicine Service," Chapter 1, "Pathology and Laboratory Medicine Service Administration," formerly titled "Laboratory Service."

2. Principal revisions include:

a. Paragraph 1.01: Defines the mission and standards for the VA medical center Pathology and Laboratory Medicine Service.

b. Paragraph 1.02: Defines the scope, establishes policy and defines organizational structure and limits of Pathology and Laboratory Medicine Services in accordance with 38 United States Code.

c. Paragraph 1.03: Defines requirements for administrative direction and test categories in VA medical centers.

d. Paragraph 1.04: Describes the functions of Pathology and Laboratory Medicine Service.

e. Paragraph 1.05: Outlines the administrative management responsibilities of the Chief, Pathology and Laboratory Medicine Service.

f. Paragraph 1.06: Establishes policy for management and trend analysis.

g. Paragraph 1.07: Establishes policy for interaction with other clinical laboratories.

h. Paragraph 1.08: Establishes requirements for medical legal practices.

i. Paragraph 1.09: Establishes policy for an intralaboratory safety and health program.

j. Paragraph 1.10: Establishes responsibilities of the Chief, Pathology and Laboratory Medicine Service, for educational programs.

k. Paragraph 1.11: Defines research responsibilities.

l. Paragraph 1.12: Establishes policy for management structure and direction.

m. Paragraph 1.13: Defines the qualifications and responsibilities of the Chief, Pathology and Laboratory Medicine Service.

n. Paragraph 1.14: Establishes policy for consultants, ancillary testing sites, and special clinical resource chiefs.

o. Paragraph 1.15: Provides graphic organizational charts for laboratories of varying size and complexity.

p. Paragraph 1.16: Provides policy for evaluating the overall management performance of the laboratory.

q. Paragraph 1.17: Provides references for Chapter 1.

3. Filing Instructions

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Cover through vii

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Insert pages

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1-i through 1-ii

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1A-1 through 1A-2

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4. RESCISSIONS: M-2, Part VI, Chapter 1, dated July 28, 1978.

S/ by Dennis Smith for
John T. Farrar, M.D.
Acting Under Secretary for Health

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CLINICAL PROGRAMS

Pathology and Laboratory Medicine Service

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Department of Veterans Affairs, Veterans Health Administration manual M-2, "Clinical Programs," Part VI, "Pathology and Laboratory Medicine Service," is published for the compliance of all concerned.

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RESCISSIONS

The following material is rescinded:

COMPLETE RESCISSIONS

a. Manuals

- M 10-6, Secs. I and II, ch. 4.
- Changes 1 through 47, 49, 50 through 56, 58 through 64, and 70.
- M-2, Part VI, Chapter 1, dated July 28, 1976, change 48.
- M-2, Part VI, Chapter 2, changes 71 and 72.
- M-2, Part VI, Chapter 2, dated July 10, 1989.
- M-2, Part VI, Chapter 3, dated July 23, 1985, change 66.
- M-2, Part VI, Chapter 4, dated November 1, 1985, change 68.
- M-2, Part VI, Chapter 5, dated August 21, 1987, change 73.
- M-2, Part VI, Chapter 6, dated July 23, 1985, change 67.
- M-2, Part VI, Chapter 7, dated September 14, 1983, change 65.
- M-2, Part VI, Chapter 8 dated March 20, 1990, and change 59.
- M-2, Part VI, Chapter 10, dated September 6, 1968, change 25.
- M-2, Part VI, Chapter 12, dated January 3, 1986, change 69.
- M-2, Part VI, Chapter 13, dated April 3, 1978, change 57.

b. Interim Issues

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d. Regulations and Procedures

- R&P 6212
- R&F 6213
- R&F 6372
- R&F 6373

e. Technical Bulletins

- TB 10A-21
- TB 10A-47
- TB 10A-68, paragraphs. 1d and 3d.

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August 30, 1950	Concerning the Procurement and Utilization of Blood
January 11, 1952	Blood Transfusions
December 28, 1953	Serologic Tests for Diagnosis of Syphilis

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RESCISSIONS

The following material is rescinded:

Manuals

M-2, Part VI, Chapter 1, dated July 28, 1976

CHAPTER 1. PATHOLOGY AND LABORATORY MEDICINE SERVICE
ADMINISTRATION

1.01 PURPOSE

a. The purpose of this chapter is to provide policy guidance for the administrative structure and management of services providing laboratory testing in Department of Veterans Affairs (VA) medical centers and their outreach functions.

b. 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.

1.02 POLICY

a. A Pathology and Laboratory Medicine Service must be established within the physical plant and geographic boundaries of all VA medical centers and major outreach facilities that diagnose and treat patients. The functions of Pathology and Laboratory Medicine Service must include both clinical laboratory medicine and anatomic pathology, including patient care, educational, developmental and research aspects. A list of the mandatory categories of tests that must be performed to provide optimum patient care within the confines of the VA medical center and its outreach functions appears in Appendix 1A.

b. The main clinical laboratory in each VA medical center will be directed by a sole Chief, Pathology and Laboratory Medicine Service, who is a licensed, board-certified pathologist, and will include clinical laboratory medicine, blood transfusion and anatomic pathology services all under the administrative direction of the Chief, Pathology and Laboratory Medicine Service.

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.

c. The applicable requirements of M-2, Part VI, must be met when any laboratory patient care services are offered, regardless of the location of pathology and laboratory medicine services. These requirements are applicable to all other laboratory elements that perform patient care tests within a VA medical center, regardless of the physical relationship to the main pathology and laboratory medicine services, or the administrative service assigned to direct the personnel, research, or technical aspects, of the test site.

d. Both direct and indirect patient care tests will be provided in accordance with 38 United States Code (U.S.C.) at each VA medical center. To support a wide scope of services to be available at each VA medical center, full advantage will be taken of regionalization, sharing and networking within the VA system before using other sources, (see Ch. 11).

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(1) In some instances all necessary laboratory services will be available in a VA tertiary care laboratory, and in others they will be met through a combination of referrals to other VA medical center laboratories, VA Special Clinical Reference Laboratories, affiliated medical school laboratories, military, and other federal laboratories.

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(2) Specialized tests that cannot be obtained from other VA medical centers within a geographic cluster of VA medical centers because of extreme physical distance between VA medical centers, or tests, that cannot be obtained from the sources noted in this paragraph, must be procured using the contract specifications identified in Chapter 11.

1.03 OPERATION OF LABORATORY SERVICES

a. Each Pathology and Laboratory Medicine Service will be directed by a Chief, Pathology and Laboratory Medicine Service, who is responsible to the Chief of Staff. This centralized position will be held at all times by a licensed pathologist who is board certified in clinical and anatomic pathology by the American Board of Pathology. NOTE: In special circumstances, when a Chief, Pathology and Laboratory Medicine Service, cannot be recruited in remote and/or rural locations, requirements for this position are given in paragraph 1.12.

b. The main clinical laboratory will perform the categories of tests listed in appendices 1A and 1B, for VA patients, when necessary, on a 24-hour, 7-day basis. The medical staff will select tests needed for immediate response. For legal protection, if these tests cannot be performed in their entirety, written permission must be obtained from the medical center Director, from the Regional Director, and the Director, Pathology and Laboratory Medicine, VA Central Office, with justification for the exception, and an explanation of how coverage for emergent tests is provided during routine and non-routine hours to satisfy quality improvement and legal requirements.

1.04 FUNCTIONS OF THE PATHOLOGY AND LABORATORY MEDICINE SERVICE

The Chief, Pathology and Laboratory Medicine Service, is responsible for directing and coordinating the functions of the service based on the mission, special needs and size of the facility. The functions of this position are diverse and those listed under encompass patient care, administration, education and research. The standard of operations will meet, or exceed, those prescribed by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), Federal, and national accrediting bodies. Accreditation by the College of American Pathologists (CAP) is mandatory.

a. Medical and/or Patient Care Functions. The physician staff of the laboratory making judgments about the medical significance of clinical laboratory data must communicate effectively in interpreting laboratory data and correlate laboratory data for clinical physicians. This function is primarily carried out at the bedside and in clinical rounds. The Chief, Pathology and Laboratory Medicine Service, may designate (in writing) qualified clinical scientists, supervisors and pathology resident physicians to assist in this function.

(1) Consultations

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(a) The physician staff of the laboratory provides consultations to clinical physicians regarding the medical significance of laboratory findings. The clinical laboratory scientist(s) and certified medical technologists provide consultation on laboratory technical findings to patient care personnel according to local policies established by each VA medical center. The Chief, Pathology and Laboratory Medicine Service, designates, in writing, who is qualified to perform consultations, and place medical diagnoses and information in patient's records.

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(b) The Chief, Pathology and Laboratory Medicine Service, and staff pathologists will be available to the hospital staff for consultation and guidance in matters pertaining to Pathology and Laboratory Medicine. The Chief, or designee, will convene and participate in professional conferences. The Chief, or designee, will participate actively in committees with responsibilities relating to patient care and safety. Such committee responsibilities include, but are not limited to the:

1. Tissue Committee,
2. Infection Control Committee,
3. Transfusion Review Committee,
4. Ancillary Testing Committee, and
5. Utilization Review Committee.

(c) The Chief, Pathology and Laboratory Medicine Service, staff pathologists and medical technology specialists in blood banking and transfusion medicine will provide expert consultation for transfusion-related problems. (See Ch. 5 for transfusion medicine policies).

(d) The Chief, Pathology and Laboratory Medicine Service, and staff pathologists will actively participate in the diagnosis of surgical and cytopathologic specimens, and interact and provide expert consultative services for attending physicians on follow-up of surgical and cytopathologic case material.

(2) Blood and Blood Component Transfusions. Pathology and Laboratory Medicine Service:

(a) Procures, tests and dispenses blood and blood components for patient treatment,

(b) Provides bedside consultations for transfusion-associated problems, and

(c) Performs investigation of technical and disease-associated problems associated with blood/component transfusion.

(3) Fine Needle Aspiration, Bone Marrow and Other Surgical Biopsies. Credentialed and qualified laboratory physicians perform and provide these diagnoses on tissues and fluids when requested by clinical physicians within the medical center and outpatient and/or satellite outreach functions, or by the physicians in affiliated university, community, military, or Federal hospitals.

(4) Surgical Pathologic and Cytopathology Examinations. This service performs gross and microscopic examinations on tissues and microscopic examinations on cytology specimens and provides reports to clinical physicians

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on these examinations. Pathology and Laboratory Medicine Service performs surgical-cytology correlation and case review for prior diagnoses for each patient from which tissue or cytologic material is received. (See Ch. 6.)

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(5) Clinical Laboratory Medicine Test Performance. The Pathology and Laboratory Medicine Service provides diagnostic and monitoring tests for use by clinical physicians, nursing staff and other health care providers whose clinical privileges or scope of practice in VA medical centers and outreach functions permits them to request and utilize tests in the diagnosis and treatment of patients (see Ch. 4).

b. Quality Improvement Functions (See Ch. 2.)

(1) Standards of Performance

(a) The Chief, Pathology and Laboratory Medicine Service, serves as the medical center's Quality Compliance Officer for all sites that perform laboratory tests for patient care.

(b) The Chief, Pathology and Laboratory Medicine Service, and laboratory physicians are be involved in quality improvement in the medical center by:

1. Establishing medical standards for utilization of the laboratory in conjunction with clinical physicians (see Ch. 3) and the medical center's Ancillary Testing Committee (see Ch. 10).

2. Defining criteria-based audits to determine when practice patterns exceed defined standards.

3. Revising testing standards when there has been a change in common usage.

4. Determining whether medical care is appropriate, safe, and adequate by measuring the outcome of medical laboratory testing in the medical center (see Ch. 14).

(c) This applies not only to transfusion practices, but also to the selection of appropriate antimicrobial therapy, the effective use of pharmacological agents, nutrition support services, anticoagulant therapy and surgical/cytology appropriateness, among other functions provided by the laboratory.

(d) The Chief, Pathology and Laboratory Medicine Service, and senior staff defines, implements, and monitors standards of:

1. Performance in quality control, and

2. Quality improvement cost-effectiveness of the main clinical laboratory and other ancillary laboratory testing programs, as appropriate.

(e) The Chief, Pathology and Laboratory Medicine Service, is responsible for ensuring continuous outcome measurement at all testing sites (see Ch. 14).

(2) Test Appropriateness Evaluation. The laboratory medical and technical staff in collaboration with clinical physicians who order tests, jointly

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participate in the monitoring and evaluation of the quality and appropriateness of patient tests appropriate for the institution, regardless of the location of the testing site(s). The pathologist/scientist/technologist team approach affects cost containment-quality improvement issues and assumes responsibility for determining which tests, test combinations, and test sequences offer the highest yield, specificity, sensitivity and

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accuracy in defined medical situations (see Ch. 3). The Chief, Pathology and Laboratory Medicine Service, is ultimately responsible for administering the test appropriateness program in the medical center.

(3) Monitoring and Correlation of Laboratory Data. The Chief, Pathology and Laboratory Medicine Service, develops a plan to monitor all work performed in the laboratory to determine that medically reliable data are being generated. Laboratory data for diagnosis and patient management is correlated between laboratory sections to provide optimum efficacy in delivery of patient care results to treating physicians and nursing staff (see Ch. 2).

(4) Reference Laboratories. The Chief, Pathology and Laboratory Medicine Service, selects all outside referral laboratories in accordance with Chapter 11, to ensure that tests are performed in reference laboratories according to the same high standards utilized by VA medical center main clinical laboratories.

(5) Ancillary and/or Point of Care Testing Sites. The Chief, Pathology and Laboratory Medicine Service, chairs the VA medical center's Ancillary Testing Committee and provides technical, accreditation, inspection and quality medical improvement oversight for all ancillary testing sites (ATS) within the VA medical center and its outreach sites that perform diagnostic, monitoring or screening tests performed on patient specimens (see Ch. 10).

(6) Postmortem Examinations. The Chief, Pathology and Laboratory Medicine Service, ensures the performance of postmortem examinations with completion of the protocol within 60 working days from date of postmortem examination. (See Ch. 9.) The Chief, Pathology and Laboratory Medicine Service, correlates premortem with postmortem diagnoses and reports discrepancies to the patient's attending physician, the appropriate clinical service chief, the VA medical center's Quality Management Coordinator, and the Chief of Staff (COS).

(7) Interaction with Physicians, Patients, Administrators, and Agencies. The Chief, Pathology and Laboratory Medicine Service, relates with and functions effectively with applicable accrediting and regulatory agencies, appropriate administrative officials, the medical staff, and the patient population served to guarantee adequate external reviews of laboratory quality.

(8) Quality Control, Proficiency Testing and Peer Review of Tests and Surgical Pathology/Cytopathology Diagnoses. The Chief, Pathology and Laboratory Medicine Service, will maintain a comprehensive quality control, proficiency testing, and peer review programs within the main clinical laboratory and all ancillary testing sites (see Ch. 2).

(9) Measurement of Patient Outcome Using Clinical Indicators and Other Outcome Measures. The Chief, Pathology and Laboratory Medicine Service, provides measures of patient outcome, utilizing the latest data available from Patient Injury Reports and other clinical indicators that show the

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laboratory's performance in providing quality of care for patients in each of the technical subsections of the laboratory (see Ch. 14).

(10) Infection Control Surveillance and/or Reporting and Investigation of Foodborne Diseases. The Chief, Pathology and Laboratory Medicine Service, shall maintain an

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active interest in the control of infections within the hospital. The Chief, Pathology and Laboratory Medicine Service, or a designee, will be a member of the Infections Control Committee.

(a) Pathology and Laboratory Medicine Service assumes responsibility for culturing material taken as check samples at frequent intervals from sites such as the operating suite or patient areas.

(b) The identification of pathogenic organisms from a source assumed to be clean or sterile shall be reported without delay to the proper authorities within the hospital (see Ch. 7).

(11) Preventive Medicine and Public Health. The Chief, Pathology and Laboratory Medicine Service, or designee, shall provide assistance in support of activities relating to preventive medicine and public health.

(a) Laboratory examination of samples of food, dairy products, water, food service utensils, food service equipment, food vending machines, and the bacteriological monitoring of floor surfaces, linens, and air flows will be conducted in accordance with the recommendations of the Infection Control Committee.

(b) Pathology and Laboratory Medicine Service will provide support for investigation of outbreaks of food poisoning, as outlined in Chapter 7.

(12) Occupational Safety and Health. The Chief, Pathology and Laboratory Medicine, will provide a safe and healthful workplace for all service employees. The Chief, Pathology and Laboratory Medicine Service, will keep the medical center's safety and health official informed on all Pathology and Laboratory Medicine issues that affect the health and safety of VA employees.

1.05 ADMINISTRATIVE MANAGEMENT RESPONSIBILITIES

The Chief, Pathology and Laboratory Medicine Service, is responsible for keeping abreast of current management trends and applying them to VA medical center laboratory operations. The duties of the Chief for management are diverse and varied. The following list includes comprehensive functions necessary for good management.

a. Financial Management. The Chief, Pathology and Laboratory Medicine Service, provides cost-effective and efficient administration of Pathology and Laboratory Medicine Service including budget planning and control with responsible financial management (see Ch. 15).

b. Human Resources Management. The Chief, Pathology and Laboratory Medicine Service, shall work with appropriate facility personnel to ensure that there are sufficient numbers and types of qualified personnel available to perform the work of the service which meets the accreditation requirements of JCAHO and CAP. This includes ensuring that physicians are properly credentialed and privileged, the qualifications and health status of other

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employees are properly documented, and interpersonal problem resolution mechanisms are established.

(1) The Chief, Pathology and Laboratory Medicine Service, ensures that procedures and tests performed by the technical staff are within the scope of education, training, and experience of the individual(s) employed to perform the tests, based on accreditation requirements of JCAHO and CAP.

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(2) The Chief, Pathology and Laboratory Medicine Service, ensures that qualified technical staff are on duty, or available, at all times that laboratory testing is being performed. Emergency laboratory testing is performed only by qualified medical laboratory personnel (see Ch. 12).

NOTE: The laboratory chief shall maintain documentation of the qualifications of technical personnel authorized to perform procedures.

c. Equipment, Supplies and Space Management

(1) The Chief, Pathology and Laboratory Medicine Service, ensures that there is sufficient space, equipment, and supplies within the Pathology and Laboratory Medicine Service to perform the required volume of work with optimal accuracy, precision, efficiency, timeliness, and safety. For guidance on space planning and design, the Chief, Pathology and Laboratory Medicine Service, is required to utilize Construction Management Planning Criteria for VA Facilities, H-08-9, Chapter 240.

(2) The performance of instruments and equipment is evaluated by the Chief, Pathology and Laboratory Medicine Service, frequently enough to ensure that they function properly at all times. Appropriate records are maintained for each item of equipment. The records must show the dates of inspections, validations, or performance evaluations, as well as significant actions taken in response to revealed deficiencies. Temperatures are recorded daily for all temperature-controlled instruments (see Ch.4).

d. Communications. The Chief, Pathology and Laboratory Medicine Service, maintains channels of communication within Pathology and Laboratory Medicine Service, with other departments and other services of the medical center, the medical staff, and with approved and accredited outside services and agencies that are appropriate for the size and complexity of the hospital. The Chief, Pathology and Laboratory Medicine Service, enforces policies in this manual that ensure the continued quality of the laboratory testing process.

(1) The Chief, Pathology and Laboratory Medicine Service, ensures that all requests for laboratory tests are made in writing or through electronic means. The policies of Medical Administration Service (MAS) are followed for guidance in this area.

(2) The Chief, Pathology and Laboratory Medicine Service, ensures that the laboratory performs tests and examines specimens only on the written request of:

(a) Individuals authorized by the medical staff to order such evaluations and receive the results.

(b) Those physicians, or non-physicians, who are not members of the medical staff but who have written authorization as designated in the medical staff by-laws and/or specific written privileges to request such support services.

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(c) Other persons, to the extent permitted by law, who are authorized by the facility and licensed to engage in the direct treatment of patients.

e. Patient Identification. The Chief, Pathology and Laboratory Medicine Service, enforces the policies in this manual to ensure that orders or requisitions for inpatient and ambulatory care patient services clearly identify:

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- (1) Patient,
- (2) Requesting individual,
- (3) Tests required,
- (4) Any special handling required,
- (5) Date and, when relevant, the time the specimen was collected, and
- (6) Date and time the request and/or specimen reached the laboratory.

f. Specimen Collection, Preservation, and Transportation

(1) The Chief, Pathology and Laboratory Medicine Service, enforces the policies in this manual to ensure that each patient specimen is in satisfactory condition for the tests to be performed.

(2) Written procedures, approved by the Chief, Pathology and Laboratory Medicine Service, are developed for those who collect specimens throughout the VA medical center.

(a) The procedures relate to at least the following:

1. The ordering of tests;
2. Standards and special methods used for the preparation of patients and the collection of specimens;
3. Precautions to be taken for special procedures; and
4. Proper identification, storage, and preservation of specimens.

(b) The Chief, Pathology and Laboratory Medicine Service, ensures that these guidelines shall be applied uniformly through the medical center.

(c) The Chief, Pathology and Laboratory Medicine Service, ensures that a record of the daily accession of specimens and an appropriate system for the identification of specimens is maintained. The record includes at the least the:

1. Laboratory test site location and patient identification;
2. Identification of the practitioner ordering the test or evaluation;
3. Date, and when relevant, time of specimen collection and receipt;
4. Reason for any unsatisfactory specimen;
5. Test or evaluation performed;

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6. Result; and

7. Date and time of reporting to the requesting practitioner or patient care unit (see Ch. 2).

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(d) A system must exist within the medical center and its outreach functions for receipt, identification, documentation, examination and reporting on all specimens submitted to each laboratory and testing site in the medical center and its outreach functions. The Chief, Pathology and Laboratory Medicine Service, as Chairperson of the medical center's Ancillary Testing Committee, is responsible for the efficient and effective functioning of this system.

(e) The Chief, Pathology and Laboratory Medicine Service, is responsible for storage and disposition of specimens according to the requirements of national inspection, accreditation and Federal safety organizations and departments; this information must be available for all testing sites.

g. Test Results. The Chief, Pathology and Laboratory Medicine Service, enforces the policies in this manual to ensure that:

(1) The laboratory report includes the date and time of reporting, and the condition of any unsatisfactory specimen.

(2) A system is developed to ensure that the individual responsible for performing or completing the procedure is identified and can be traced to the site where the test was performed.

(3) A list of critical limits of tests is published and distributed to all patient care areas of the medical center and its outreach sites.

(4) Criteria are established for the immediate notification of the provider responsible for the care of the patient when critical limits of specified test results are exceeded. The Clinical Executive Board and Credentials Committee of the medical center will determine which persons are considered providers.

h. Results Reporting

(1) The Chief, Pathology and Laboratory Medicine Service, enforces the policies in this manual that require records and reports to be maintained and, as appropriate, are filed in the patient's record and in Pathology and Laboratory Medicine Service for time periods specified by JCAHO and CAP.

(2) Authenticated, dated reports of all examinations performed by Pathology and Laboratory Medicine Service are made part of the patient's medical record.

(a) The Chief, Pathology and Laboratory Medicine Service, enforces the policies in this manual to ensure the accurate and prompt reporting of all laboratory testing results produced in the medical center.

(b) When tests are performed in a reference laboratory, the name of the laboratory performing the test is included in the report placed in the patient's record (see Ch. 11).

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(3) The Chief, Pathology and Laboratory Medicine Service, ensures that a descriptive diagnostic report of gross specimens received (and of autopsies performed) is produced for every specimen received. Diagnoses made on surgical specimens and autopsies must be expressed in acceptable terminology of a recognized disease nomenclature; these must be indexed for retrieval (see Ch. 6).

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(4) Reports of all anatomic and clinical laboratory medicine tests and examinations performed must be readily available to the individual ordering the tests. The facility ensures that the reports are filed promptly in the patient's record. JCAHO's requirement for providing reference values may be met by including in the medical record a current listing of such values. The VA medical center's Ancillary Testing Committee must concur on the content and range of values for ancillary testing sites. The basis on which the reference values in use were established is available to medical staff members upon request.

(5) The Chief, Pathology and Laboratory Medicine Service, is responsible for standardizing the Decentralized Hospital Computer Program (DHCP) cumulative laboratory reporting form throughout the medical center and actively works with the chiefs of all ATS in the medical center to maintain the same methods and reference values for each test type (see Ch. 10).

NOTE: Duplicate copies of the reports of all anatomic and clinical laboratory tests and examinations performed are retained in the laboratory in a readily retrievable manner.

1.06 MANAGEMENT DATA AND TREND ANALYSIS

a. The Chief, Pathology and Laboratory Medicine Service, is responsible for establishing a laboratory management data collection system, using DHCP and management systems noted in Chapter 15.

b. The Chief, Pathology and Laboratory Medicine Service, analyzes and relates the data to assess cost-effectiveness, staffing, equipment and space needs. The VA medical center Director, and COS will be apprised of changing conditions and needs through documented recommendations prepared by the Chief, Pathology and Laboratory Medicine Service.

c. The Chief, Pathology and Laboratory Medicine Service, reviews productivity information for the reporting period. Laboratory productivity level is compared to peer groups as determined by Pathology and Laboratory Medicine Service, VA Central Office (see Ch. 15).

1.07 INTERACTION WITH MILITARY, FEDERAL, STATE AND PRIVATE SECTOR LABORATORIES

a. The Chief, Pathology and Laboratory Medicine Service, will cooperate with the clinical laboratories of military, Federal, State, private agencies, and medical institutions in such matters as proficiency surveys, reference or referee laboratory surveys, and exchange of data for the advancement of laboratory medicine.

b. Laboratory tests may be preformed for other healthcare organizations and agencies when so requested in case of emergency when the volume is such that it will not interfere significantly with normal operations (see Chs. 11 and 18).

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1.08 MEDICAL LEGAL RESPONSIBILITIES

a. The Chief, Pathology and Laboratory Medicine Service, will remain cognizant of local medical legal practices and resources, and will comply with the local practices to the extent permissible by VA regulations.

b. Assistance with special forensic post-mortem cases may be obtained from the Armed Forces Institute of Pathology (See Chs. 11 and 18).

c. Toxicological examinations that are not available locally may be obtained from other VA sources (see Ch. 8).

1.09 SAFETY AND HEALTH

The elements of a Laboratory Safety and Health Program are identified in Chapter 15. In addition to the requirements of Chapter 15, the service chief will ensure that appropriate security precautions are observed by employees and visitors to the laboratory.

1.10 EDUCATION RESPONSIBILITIES

a. VA medical center Pathology and Laboratory Medicine Services, are committed to the principles of education of all laboratory physicians, clinical scientists, and technical personnel, and will maintain and encourage affiliation with schools of medicine, universities, colleges, and professional organizations that provide laboratory training programs.

b. The Chief, Pathology and Laboratory Medicine Service, provides educational direction for the medical and laboratory staff, and participates in educational programs of the institution as appropriate. This includes, but is not limited to the following:

(1) Provision for all personnel, including physicians and supervisors, to further their knowledge and skills through on-the-job training, in-service education programs, or attendance at workshops, institutes, and/or professional meetings. An in-service education program shall be provided at defined intervals appropriate for the size and needs of the technical staff. The program content and personnel participation shall be documented.

(2) Maintenance of continuing educational programs for professional and technical personnel. Members of the laboratory staff will be encouraged to attend and participate in the programs of professional organizations, including short courses, workshops and meetings at local and national levels. Such activities are a necessary adjunct to maintaining and expanding professional knowledge and skills. An orientation program shall be provided for each new laboratory employee, and the employee's participation shall be documented.

(3) Establishment and maintenance of accredited educational programs for the training of residents and allied health personnel in VA medical centers with Deans Committees or Medical Advisory Committees. In selected VA medical centers with such affiliations, training programs for resident physicians and allied health personnel may be conducted.

1.11 RESEARCH AND DEVELOPMENT RESPONSIBILITIES

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Clinical research in Pathology and Laboratory Medicine is the basis for innovation and improvement in the quality of patient care, and is essential for the expansion of services, especially in areas directly related to the special problems of the aging and disabled veteran.

- a. The Chief, Pathology and Laboratory Medicine Service, shall:

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(1) Foster clinical research as an integral part of the program, recognizing that the benefits are direct and indirect for improving the quality of care for patients.

(2) Plan and direct research and development appropriate to the facility.

b. VA Pathology and Laboratory Medicine Service personnel are encouraged to apply for grants and joint research projects with VA, private, Federal and non-Federal agencies that support clinical research.

1.12 MANAGEMENT STRUCTURE AND DIRECTION

Pathology and Laboratory Medicine Service (the main, central laboratory in a VA medical center) must be directed at all times by a physician who is a licensed, board certified pathologist, and who is qualified by virtue of documented training, expertise, and experience to assume professional, scientific, consultative, organizational, administrative, educational and clinical research responsibilities for the laboratory and for services rendered.

a. In a VA medical center where Pathology and Laboratory Medicine provides clinical consultation, blood transfusion, surgical and/or cytopathology, and/or medical diagnostic/interpretive opinions, the Chief, Pathology and Laboratory Medicine Service, must be board certified in both anatomic and clinical pathology. In the event that the VA medical center cannot recruit a pathologist who is board certified in both specialties, a pathologist must be employed on at least a 5/8ths basis who is board-certified in the specialty (either anatomic or clinical pathology) that is not possessed by the Chief, Pathology and Laboratory Medicine Service, so that the VA medical center is ensured complete coverage for both specialties.

b. Because of the legal responsibilities that encumber the Chief's, Pathology and Laboratory Medicine Service position, it must be filled at all times by a licensed, board-certified physician, even when the position is held by a temporary and/ or acting Chief, Pathology and Laboratory Medicine Service.

1.13 QUALIFICATIONS, RESPONSIBILITIES, AND ROLE OF THE CHIEF, PATHOLOGY AND LABORATORY MEDICINE SERVICE

a. The keystone and most fundamental principle of VA clinical laboratory testing operations is continuous quality improvement of patient care. The importance of the laboratory in present-day medicine is underscored by its major role in the delivery of services related to all health care activities within a medical center.

b. The Chief, 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

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appropriate training and background to be able to discharge the responsibilities cited in this chapter. January 31, 1994

c. Responsibilities accruing to the Chief, Pathology and Laboratory Medicine Service, have become multidirectional. Professional medical, as well as managerial skills are needed and must be integrated for the successful operation of a laboratory. The Chief, Pathology and Laboratory Medicine Service, is responsible for:

(1) Maintaining the highest standards of quality for every aspect of laboratory operation.

(2) Technical innovations in laboratory methodology and data handling, as well as cost-effective and imaginative utilization of personnel skills and equipment.

(3) Working with and managing human resources and solving interpersonal problems that may promote good working relationships.

c. Delegation of Responsibilities. The Chief, 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 and technical responsibilities to qualified laboratory personnel as appropriate. The Chief, Pathology and Laboratory Medicine Service, however, remains responsible for the overall operation and administration of the laboratory to ensure that quality patient services are provided and that personnel operations and laboratory management runs smoothly and efficiently.

1.14 OTHER PERSONNEL

a. Consulting Pathologists

(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 main laboratory, the services of a board-certified, qualified, licensed consulting pathologist shall be retained.

(a) The consulting pathologist shall be a member of the Clinical Executive Board, and all quality improvement committees.

(b) A close working relationship between the COS and the consulting pathologist must be established.

(c) The Chief Technologist and consulting pathologist must establish an effective working relationship with the institution's administration, the laboratory's management and staff, the medical staff, and, where appropriate, other institutional departments and services.

(d) The consultant shall play an active role in the educational programs of the laboratory and of the institution.

(2) When the services of the pathologist are limited to those of consultant status, these services shall be provided on a regular (preferably at least twice-weekly) basis.

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

(b) The consultant shall sign in and out at each visit in the office of the COS on official VA log sheets.

b. Requirements for Chiefs of Laboratories Not Requiring Surgical Pathology, Cytopathology or Transfusion Medicine/Blood Bank Services

(1) In laboratory ATS outside the physical limits of the main VA medical center's Pathology and Laboratory Medicine Service, a non-pathologist physician or doctoral scientist may serve as Chief, Pathology and Laboratory Medicine Service. This individual must be qualified by virtue of documented training, expertise, and experience in the areas of analytical testing, biological, chemical or clinical science specially related to the ATS's special testing functions. In each and every ancillary testing site, including bedside and point of care sites, the services of a qualified consulting pathologist shall be provided by an in-house laboratory physician in the main VA medical center laboratory.

(2) In all ATS sites, the Chief, Pathology and Laboratory Medicine Service (or designated in-house consultant who is a board-certified pathologist) will provide signatory support for the legal backup for medical interpretive reporting when the ATS Chief is a doctoral scientist. In each and every ATS the VA medical center's Ancillary Testing Coordinator will provide quality improvement oversight when the ATS Chief is a non-pathologist physician (see Chs. 10 and 2).

c. Chiefs of Special Clinical Reference Center Laboratories. Special clinical reference center laboratories refer to both clinical and clinical support services in VA medical centers for all types of clinical diagnostic resources that do not involve the transfer of patients from one VA medical center to another.

(1) Clinical activities that may be included in a Special Clinical Resource Center (SCRC) will be restricted to: analysis of specimens or data, and the supply of unique devices, materials and/or biologicals not requiring the presence of a patient.

NOTE: VA medical centers are encouraged to develop new SCRC's in addition to those special reference centers already operational such as those laboratories for virology, tuberculosis, cytogenetics, radioimmunoassay, etc. (see Ch. 11).

(2) The following requirements must be followed for a Chief, SCRC:

(a) The Chief, SCRC, may be a doctoral scientist, non-pathologist physician, or pathologist, board certified in either anatomic pathology or clinical pathology.

(b) When the SCRC performs any one or all tests in an anatomic pathology subspecialty or in blood banking (immunohematology), the Chief, SCRC must be a board-certified pathologist in the specialty related to the services performed.

1.15 ORGANIZATIONAL STRUCTURE OF LABORATORY SERVICES

The following recommended organizational structures are provided for use in determining staffing patterns for laboratory personnel in VA medical centers

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of varying size and complexity. See Appendix 1B for guidelines on determining
a laboratory's complexity.

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a. General Structure. Main Clinical Laboratories and Ancillary Testing Laboratories:

~~(Chart could not be reproduced on WANG - copies may be obtained in CMD Library Room 662 TW)~~

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b. Very Large, Large and Medium Complexity Laboratories

~~(Chart could not be reproduced on WANG — copies may be obtained in CMD Library Room 662 TW)~~

c. Small Laboratories, Free-Standing Outpatient Clinics and Satellite Outpatient Clinics

~~(Chart could not be reproduced on WANG — copies may be obtained in CMD Library Room 662 TW)~~

1.16 ADMINISTRATIVE MANAGEMENT PERFORMANCE MEASURES

All VA medical center Chief, Pathology and Laboratory Medicine Service,s of Pathology and Laboratory Medicine are responsible for the smooth and coordinated operation of the service. The criteria for evaluating the overall performance of the laboratory are discussed in Chapter 15.

1.17 REFERENCES

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a. Accreditation Manual for Hospitals. Joint Commission on Accreditation of Healthcare Organizations, One Renaissance Blvd., Oakbrook Terrace, IL 60181, 1992.

b. Standards for Laboratory Accreditation. The College of American Pathologists Laboratory Accreditation Program, 325 Waukegan Road, Northfield, IL 60093-2750, 1992, pp.1-3.

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BASIC LABORATORY SERVICES THAT MUST BE PERFORMED IN ALL MAIN
CLINICAL LABORATORIES WITHIN VA MEDICAL CENTERS
AND MAJOR OUTPATIENT CLINICS

Each VA medical center's main clinic laboratory must have the capability to perform:

- a. Hematology and Coagulation Studies (Immediate Response (I.R.) and Routine).
- b. Chemistry (Clinical Chemistry) (I. R. and Routine), including tests for:
 - (1) Electrolytes,
 - (2) Renal Function,
 - (3) Liver Function,
 - (4) Cardiac Tests,
 - (5) Isoenzymes,
 - (6) Lipid Tests (Routine use only),
 - (7) Osmometry,
 - (8) Blood Gases, and
 - (9) Therapeutic drug monitoring, Toxicology, and drug abuse screening and monitoring.
- c. Microscopic Examination and Organism Isolation (Routine and I.R.) (Microbiology).
- d. Culture (Microbiology) of blood, body fluids, exudates and environmental/infection control cultures (Routine and I.R.).
- e. Susceptibility Tests (Microbiology), (Routine and I. R.).
- f. Mycobacteriology (Routine).
- g. Mycology (Routine).
- h. Parasitology (Routine).
- i. Urinalysis (Routine and I.R.).
- j. Blood Bank, Transfusion Medicine and Immunohematology (Routine and I. R.).

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k. Diagnostic and General Immunology (Routine, including Acquired Immune Deficiency Syndrome (AIDS)/Human Immunodeficiency Virus (HIV) antibody testing.

NOTE: Medical centers without staff, equipment or expertise to perform these tests should refer them to the VA National Serology Reference Laboratory (see Ch. 11).

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- l. Histology (Anatomic Pathology) (Routine and frozen sections).
- m. Cytology (Anatomic Pathology).
- n. Autopsy (Anatomic Pathology).

LABORATORY COMPLEXITY INDEX - PATHOLOGY AND LABORATORY MEDICINE

All facilities must provide Basic Laboratory Services* which include:

Cardiac tests, routine and Immediate Response clinical chemistry, coagulation (Immediate Response and routine), culture (micro), cytology, drug monitoring, electrolytes, hematology (Immediate Response and Routine), immunology (routine), isoenzymes, lipid tests, liver function tests, microscopic exam and organism isolation, mycobacteriology, mycology, bacteriology, osmometry, parasitology, renal function, susceptibility testing, serologic studies including AIDS/HIV antibody testing, therapeutic drug monitoring, toxicology screening, urinalysis.

CATEGORY:

Small Medium
Outpatient

Special Clinical
Large Very Large
Resource Centers

TYPE:

Core Level 1
Level 1 Referral Level 2
Facilities
Facilities
Referral

Core Level 2 Referral
Independent OPC
Facilities Facilities
or Domiciliary Specialty

With inpatient
Same as Core
Basic Laboratory
and/or outpatient
Levels 1 and 2
Services with
surgery, mandatory
and may also
Outpatient Surgery,
services include:

Tertiary Testing

services based on

expertise of each

Same as
*Basic Laboratory
Micro- Referral Level 1
Services (App.1A)
scopy, GLC mass
Routine Histology
Surgical Pathology
spectroscopy,
Cytology
Cytology

Same as include:
must include: SCRC's staff
Referral Level 1 Electron
Surgical Pathology

Immunofluorescence,

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Routine Histology
Radioimmunoassay,
Post-mortem

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examination
Special chemistry/
 endocrine
 reference lab
Toxicology
 reference lab
Flow cytometry
Cytogenetics
Microprobe analysis
Muscle biopsy/
 histology/
 histo-chemistry
Mycobacterial
 disease/TB
 reference lab

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Core Level 1 Facilities	Core Level 2 Facilities	Referral Level 1 Facilities	Referral Level 2 Facilities	Independent C or Domiciliar
-------------------------	-------------------------	-----------------------------	-----------------------------	-----------------------------

Virology
 reference lab
 Crystal indentifi-
 cation reference
 lab
 Hemoglobinopathies
 Mycology suscepti-
 bility testing
 Serologic lab
 (special)

Core Level 1 facilities must provide the range of services identified as basic clinical services, plus services mandatory for Core Level 1. They may also provide services identified as discretionary for Core Level 1 if program criteria are met and Core Level 1 facilities have inpatient hospital capability. They provide primary care to veterans residing in their catchment area. Patients requiring most secondary and all tertiary care are referred to other facilities.

Core Level 2 facilities must provide the range of services identified as basic clinical services, the services which are mandatory for Core Level 1 facilities and may provide services which are discretionary for Core Level 1. In addition, the template identifies additional mandatory and discretionary services specifically for Core Level 2 facilities. Core Level 2 facilities may be privileged to provide selected secondary services, usually due to geographic

Referral Level 1 facilities serve as network resources for for multiple secondary and tertiary programs which are considered appropriate for the network level. These facilities must provide the range of services identified as basic clinical services, the services which are mandatory for Core Level 1 and 2 facilities and may provide services which are discretionary for these levels. The template identifies network referral services which are specifically mandatory or discretionary for Referral Level 1

Referral Level 2 facilities serve as regional or national referral resources for selected programs. Referral Level 2 facilities must provide the range of services identified as basic clinical services, services which are mandatory for Core Levels 1 and 2 and referral level 1, and may provide services which are discretionary for these levels. Referral level 2 facilities potentially serve a population extending beyond network service areas and may have national programs extending beyond regional boundaries. In some cases, a

Independent facilities must provide the range of services identified as basic clinical services, plus discretionary programs which exist if programmatic criteria are met. These facilities provide patient care which may range from primary care to highly sophisticated outpatient services. They have no inpatient hospital component but may have nursing home domiciliary k

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Core Level 1 Facilities	Core Level 2 Facilities	Referral Level 1 Facilities	Referral Level 2 Facilities	Independent C or Domiciliar
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location or unique characteristics of their veteran populations. Core Level 2 facilities serve primarily in their own catchment areas; however, they may accept referrals for secondary services (such as inpatient surgery).

facilities. Although this level primarily serves the network, this does not preclude referral relationships with facilities outside the network. Referral programs may exist at one or more, but not all facilities in the network. In some cases, a facility's population base may warrant providing network level programs even though that facility serves its own

network's population base may warrant providing regional level programs even though the program serves primarily the network. Referral Level 2 programs may exist in one or more, but usually not all networks in the region.

catchment area