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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 11, "Reference Laboratory Testing." Brackets have not been used to indicate changes.

2. Principal changes are:

- a. Paragraph 11.01: Defines the purpose of the chapter.
- b. Paragraph 11.02: Sets the policy to be followed to implement reference laboratory.
- c. Paragraph 11.03: Defines VA Central Office responsibilities.
- d. Paragraph 11.04: Defines functions of a VA Reference Laboratories.
- e. Paragraph 11.05: Defines the functions of Federal Reference Laboratories.
- f. Paragraph 11.06: Defines the process for using non-VA Reference Laboratories.
- g. Paragraph 11.07: Defines VA's Special Reference Laboratory for Pathology at the Armed Forces Institute of Pathology in Washington, DC.

3. Filing Instructions

Remove pages

11 through 12

Insert pages

11-i through 11-ii

11-1 through 11-10

11A-1 through 11A-2

11B-1

11C-1 through 11C-16

4. RESCISSIONS: M-2, Part VI, Chapter 3, dated July 23, 1985; M-2, Part VI, Chapter 4, dated November 1, 1985; and, VHA Circular 10-92-018.

~~S/3/14/94 by Dennis Smith for~~
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Acting Under Secretary for Health

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RESCISSIONS

The following material is rescinded:

a. Manuals

M-2, Part VI, Chapter 3, dated July 23, 1985
M-2, Part VI, Chapter 4, dated November 1, 1985

b. Circulars/Directives

10-92-018

CHAPTER 11. REFERENCE LABORATORY TESTING

11.01 PURPOSE

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

11.02 POLICY

NOTE: Pathology and Laboratory Medicine Service has encountered problems with the credibility, accuracy, timeliness and high cost of tests in certain private sector reference laboratories. This policy was developed to avoid any further problems and to establish sound criteria for selection of a safe and reliable reference laboratories for VA patient care.

a. A reference laboratory testing service is defined as a laboratory testing service obtained from a laboratory outside the VA medical center's main clinical laboratory. These services are required for diagnostic tests that the main clinical laboratory is unable to perform in sufficient volume to be cost-effective, or tests that a VA medical center laboratory does not have the equipment, adequate staff, or the expertise to perform.

b. VA reference laboratories in the field of pathology are established as authorized by the Director, Pathology and Laboratory Medicine, VA Central Office. Collaboration with other federal departments and agencies is encouraged.

c. Both direct and indirect laboratory tests for patient care 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 available at each VA medical center, reference tests will be obtained by regionalization, sharing and networking within the VA system before non-VA contracts are considered. In some instances, necessary laboratory services will be available in VA tertiary care laboratories. In others, they will be met through a combination of referrals to other VA medical center laboratories, VA Special Clinical Reference Laboratories (see par. 11.05) affiliated medical school laboratories, military, other federal laboratories and contracts with non-VA laboratories (see par. 11.07). NOTE: The latter sources will be used for 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.

d. Policy guidance was obtained from subject matter experts from VA field facilities in conjunction with VA Central Office Pathology Service, the Office of Acquisition and Materiel Management, and General Counsel.

11.03 VA CENTRAL OFFICE RESPONSIBILITIES

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The Director, Pathology and Laboratory Medicine Service, is responsible for:

a. Establishing standards, determining the scope of activities, providing professional and technical assistance, and recommending the necessary financial support for VA reference laboratories;

b. Correlating information transmitted by reference laboratories for use in evaluation, direction and development of the Pathology and Laboratory Medicine Service Program;

c. Maintaining liaison with the Associate Chief Medical Director for Operations and Regional Directors; and

d. Establishing liaison with the VA's National Cost Containment Center (NCCC) and other VA fiscal management, regional and Central Office programs to ensure that both VA and non-VA reference laboratories provide the most cost-effective tests at the highest level of quality.

11.04 FUNCTIONS OF VA REFERENCE LABORATORIES

a. Performance of Special Procedures. Reference laboratories within the VA system will supply, on request, assistance in the performance of special procedures for other VA medical centers whenever possible. VA reference laboratories will ensure that all referring VA medical center laboratories are kept informed of new and changing procedures. NOTE: This referral opportunity should not constitute a substitute for normal growth of laboratory activities. Tests will be performed and results transmitted in conformance with Chapter 2, "Quality Management."

b. VA Reference Laboratory Responsibility. The Chief, Reference Laboratory, is responsible for the successful operation of the Reference Laboratory, and for the conduct of business contacts which solely benefits the medical center. If allocated funds are sufficient, if workload backlogs occur, or if other problems develop that cannot be resolved by local adjustment or action, the Chief will call this to the attention of the medical center Director.

c. Establishing SCRCs. Reference laboratories, established at a VA medical center to perform a wide variety of highly specialized reference services, are known as Special Resource Centers (SCRC) (for the present list, see App. 11A). VA medical centers are encouraged to establish SCRCs by the following procedures:

(1) Size. The minimal size service area for proposed SCRCs is suggested as a geographic cluster area and may range up to national level.

NOTE: Whenever it is deemed advisable to relocate a VA SCRC laboratory, or establish a new one, the Director, Pathology and Laboratory Medicine Service, will recommend the proposed action to the Associate Deputy CMD for Operations.

(2) Proposals

(a) Proposals may be submitted at any time. All proposals for new SCRCs must originate with a VA medical center Director.

(b) Proposals to become a SCRC are to be sent from the VA medical center Director to the Regional Director and then to the Associate Chief Medical Director(AsCMD) for Operations. The AsCMD for Operations will be responsible

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for consultation with Clinical Affairs, Research Resource Management and other appropriate offices and services regarding each proposal.

(c) Each proposal must specifically show cost accounting for the SCRC, reflecting total costs as derived from such factors as equipment, consumables, research activities, educational activities, patient care, outside support and other components of total cost. From that, the critical volume for break-even point should be projected and specific

plans for marketing activity should be noted that might include sharing agreements with Department of Defense (DOD), local universities, the private sector, as well as intra-VA marketing.

(3) Funding

(a) Funding from VA Central Office is not available to initiate SCRCs. Market analyses should be completed prior to submission of a proposal. Charges for laboratory services performed by a VA medical center SCRC may be made to VA medical centers through collaboration with or between VA Regional Director's Offices.

(b) Medical center directors should agree to credit all payments received by the medical center back to the SCRC. Medical centers will be allowed to retain funds received beyond their costs, but there must be full expenditure of these payments for center-related supplies, equipment and personnel services prior to the end of the fiscal year in which these monies are received. In Regions where there is more than one center, the costs, service, and time for response will be factors in determining the survival of each SCRC in a system that interacts not only within VA, but with the non-VA sector.

(c) VA Central Office Operations will allow flexibility regarding equipment purchase and cost-accounting methods used. Similarly, VA medical centers are given flexibility in terms of calculation of amortization of equipment and overhead costs.

(d) Sharing agreements for specialized medical resources are encouraged from non-VA facilities and will provide for reciprocal reimbursement based on a charge which covers the cost of services rendered, supplies used and including normal depreciation and amortization costs of equipment in accordance with U.S.C. Section 8153(b).

(4) Medical Center Director responsibilities. The medical center Director will be responsible for:

(a) Managing the fiscal aspects of the program including actual costs developed through cost accounting and determination of test charges.

(b) Judging the success of the SCRC. The criterion for success of a SCRC will be financial self-sufficiency. It will be the responsibility of the VA medical center Director to judge the success of the SCRC. If the SCRC is felt to be failing, the Director will be responsible for adjusting charges, number of personnel, and other factors to maintain services or to submit a plan for the timely and orderly phase-out of that SCRC. Patient care must not be disrupted. If a SCRC is not successful, the Director will be responsible for planning an orderly phase-out so as not to interfere with the continuity and quality of patient care.

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(c) Making the individual medical center Director the "responsibility center" will allow the calculation of a charge that will be competitive and attract workload from other VA medical centers, DOD in accordance with 38 U.S.C. Section 8111, and from affiliated health care institutions through sharing agreements.

d. Training. VA reference laboratories will provide short periods of training for selected personnel in accordance with need. Field facilities will furnish transportation and per diem for trainees.

e. Consultation. VA reference laboratories will provide consultative service in their specialized aspect of laboratory medicine and/or pathology.

f. Clinical Activities. Clinical activities may be included in a SCRC, but will be restricted to:

(1) Analysis of specimens, or data; and

(2) The supply of unique devices, materials and/or biologicals not requiring the presence of a patient.

NOTE: In a survey of clinical services, including dentistry, it was found that many services and section chiefs included clinical services that may be offered in a center. It is not the intent of this proposal to include clinical service activities involving the movement of a patient or hands-on-patient care activities. For instance, analysis of telemetry data from imaging techniques may be performed by a center, but not the direct patient transfer to another VA medical center for performance of the imaging.

11.05 FEDERAL REFERENCE LABORATORIES

a. All VA medical centers will utilize the services of laboratories in DOD and other federal departments and agencies whenever possible and practical.

b. Two special arrangements have been established by VA Central Office which must be used for anatomic pathology, the Armed Forces Institute of Pathology(AFIP), and certain viral studies, the Center for Prevention and Disease Control (CDC) as follows:

a. The VA Reference Laboratory for Anatomic Pathology is at the AFIP, Washington, DC (see par. 11.07).

b. The Virus Reference Unit, CDC, Atlanta, GA, provides reference service for viral and rickettsial isolation studies. The CDC requirements for collection and shipment of specimens is to be followed. The requisition form CDC 3.203 will be used in requesting the reference service. A separate form is to be submitted with each specimen. NOTE: The requisition forms will be obtained from Data and Specimen Handling, Laboratory Section, Center for Infectious Diseases, Center for Disease Control, Atlanta, GA 30333.

11.06 NON-VA REFERENCE LABORATORIES

a. When reference laboratory services are required that cannot be obtained from the VA SCRC network (see App. 11A), DOD, other federal medical laboratories, or through sharing agreements with VA-affiliated health care providers, then an Request for Proposal (RFP) must be established with the desired reference laboratory, using the guidelines in M-1, Part I, Chapter 17, "Contracts, Sharing Agreements and Business Arrangements."

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b. Questions regarding this chapter should be directed to the Director, Pathology and Laboratory Medicine Service in VA Central Office.

c. Guidelines for developing a RFP for Reference Laboratory Testing Services in non-VA laboratories are given in Appendix 11C. Only Sections B, C, D, F, L, and M are included in Appendix 11C. Other applicable uniform contract format sections should be provided by the Office of Acquisition and Materiel Management.

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11.07 VA SPECIAL REFERENCE LABORATORY FOR PATHOLOGY AT THE ARMED
FORCES INSTITUTE OF PATHOLOGY, WASHINGTON, DC

a. Services Provided by the VA Special Reference Laboratory for Pathology. A VA Special Reference Laboratory for Pathology was established at AFIP on July 1, 1968. The services provided by the VA Special Reference Laboratory for Pathology were in response to the changing needs and growing emphasis on impartial peer review and quality assessment in Laboratory Services. As of November 1, 1991:

(1) The Systematic External Review of Autopsies (SERA) Program was discontinued.

(2) The Systematic External Review of Surgicals (SERS) Program continues as previously established.

(3) All cases for quality assessment continues to be selected by organ system on a scheduled basis rather than a random selection process.

(4) The organ systems chosen correspond to the most frequent sources of surgical pathology accessions in VA as well as the most referrals seen by AFIP under the present SERS Program.

b. Functions of VA Special Reference Laboratory For Pathology at AFIP. The VA Special Reference Laboratory for Pathology at AFIP will:

(1) Provide consultation services on surgical material when requested by pathologists to review:

(a) Surgical cases under the SERS Program.

(b) Cases of special interest forwarded by VA pathologists.

(2) Provide consultation and complete processing, if desired, on enucleated eyes.

(3) Provide the following special reference services for VA pathologists:

(a) Special Registry of Former Prisoners of War (see Ch. 4).

(b) Complete study of brain biopsies including electron microscopy when indicated (see Ch. 4).

(c) Complete study of muscle biopsies (see Ch. 4).

(d) Microradiographic analysis of tissue for residuals of diagnostic contrast media (see Ch. 4).

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- (e) Crystallographic studies of tissue (see Ch. 4).
- (f) Forensic autopsy service when requested for toxicology studies (see Ch. 4).
- (g) Special studies or specimens obtained from Desert Storm veterans.
- (4) Support the operation of the VA/AFIP Histopathology Quality Assessment Program.

(5) Handle the mailing and interagency coordination of case materials for the VA/AFIP Cytopathology Proficiency Testing Program.

(6) Review Board of Veterans Appeals cases.

c. Other Relationships Between VA and AFIP. Other relationships existing between VA and AFIP are those concerned with activities such as the loan of study material, attendance of VA employees at AFIP educational programs, and medical research. These relationships should be continued as they are not influenced by the establishment of the VA Special Reference Laboratory for Pathology at AFIP.

d. Channels of Communication. Direct correspondence between VA pathologists and AFIP is authorized. All such communications will be addressed to the Director, Armed Forces Institute of Pathology, Washington, DC 20306-6000.

e. Selection of Cases and Preparation of Material for Transmission to the AFIP

(1) Consultation Service. VA pathologists may send surgical material cases to the AFIP for consultation when the opinion of the AFIP staff is needed to assist in reaching a diagnosis. A completed SF 515, Medical Record - Tissue Examination, including the VA pathologist's diagnosis and indicating the points on which consultations are sought, will accompany all cases. Cases may be shipped individually as the need for consultation arises. In accordance with the urgency, cases will be marked "Telegram", "Rush", or "Routine". The Director, AFIP, has agreed to send a prompt written consultation report on each case. Consultation service autopsy cases should be clearly identified on the AFIP accession as such to distinguish them from the SERS cases reviewed routinely in accordance with the following subparagraph (2)(b).

(2) SERS Program

(a) The Chief, Pathology and Laboratory Medicine Service, at each VA medical center where surgical and cytology specimens are examined will select and forward to AFIP three significant surgical pathology cases every other month for a total of 18 cases a year. The cases selected should be from material accessioned during the preceding 12 months. For example, cases selected for examination at AFIP for January should be from skin, gastrointestinal and pulmonary systems. If a surgical case has related cytology material, this material must be forwarded with the case. The cases will be shipped to the AFIP no later than the last working day of December, February, April, June, August, and October, in order to arrive during the month scheduled for SERS cases to be reviewed.

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(b) Selection of cases will be at the discretion of the Chief, Pathology and Laboratory Medicine Service, but must include cases diagnosed by each pathologist on the staff.

NOTE: For example, if there are four pathologists performing surgical pathology examinations, the chief will assure that an equal number of cases from each pathologist is sent to AFIP over a 1-year period. The purpose of the program is to assess the quality of diagnosis for the service as a whole, as well as the quality of each pathologist's diagnosis.

(c) Cases will be identified by stamping or writing in block letters "SERS" in the upper right corner of the SF 515. In addition, "rush", "telegram", or "routine", as appropriate, will be indicated.

(d) Each case will consist of a completed SF 515, a set of stained slides and, when feasible, blocks and/or wet tissue as appropriate. Inclusion of photographs and X-rays is encouraged for review with return of the originals.

(e) AFIP will respond within 30 days to all SERS cases with comments on significant features. Quarterly reports of participation by VA medical centers will be provided by AFIP to the Director, Pathology and Laboratory Medicine Service (111F), VA Central Office, 810 Vermont Avenue, NW, Washington, DC 20420.

f. Cases of Special Interest, Enucleated Eyes and Related Specimens

(1) VA pathologists may send cases of unusual interest to the AFIP. Generally, such cases will be forwarded because they may be of value to the pathology registries.

(2) Enucleated eyes may be forwarded to the AFIP after fixation in 10 percent buffered formalin without further processing.

(3) Material may be sent to AFIP because of participation in a VA-AFIP cooperative research study.

g. Special Reference Services. Special reference services are services established to supplement facilities which exist in the VA, or facilities which have satisfactorily established arrangements with affiliated medical schools and/or other institutions. These include:

(1) Former Prisoners of War (POW) Registry. A special Former POW Registry was established in 1980 at AFIP for pathological material from former POW's of World War II (WWII), the Korean Conflict, Vietnam Era, and the Persian Gulf Crisis.

(a) All pathological material (surgical, cytologic, and autopsy) from POW's will be promptly examined and reported in the customary manner at each medical center.

(b) All VA medical centers are required to forward to the AFIP a duplicate set of slides, blocks, and representative wet tissue.

(c) All material for shipment to AFIP will be packaged in the usual manner and addressed to the Director, Armed Forces Institute of Pathology, "Attention Former POW Registry."

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NOTE: Obtaining permission for complete autopsy examination on former POW's is strongly encouraged. Such examinations should be as complete as possible with particular attention directed toward evidence of disability or injury related to evidence of stress, malnutrition, avitaminoses, and parasitic disease. These requirements are covered in considerable detail in Chapter 9, Appendix 9B.

(2) Brain Biopsy Service. On request of interested VA pathologists, AFIP will supply explicit directions for collection of specimens and containers filled with appropriate

fixative. In all cases, a duplicate set of slides and electron micrographs, if electron microscopy is performed, and a written report will be sent promptly to the referring VA pathologist.

(3) Muscle Biopsy Service. On request of interested VA pathologists, AFIP will supply explicit directions for collection of specimens and containers filled with appropriate fixative. In all cases, a duplicate set of slides and electron micrographs, if electron microscopy is performed, and a written report will be sent promptly to the referring VA pathologist.

(4) Microradiographic Studies. To participate in Microradiographic studies, VA pathologists will submit tissue fixed in buffered neutral formalin from patients who have received, within a period of 3 months, a parenteral radiographic contrast medium for angiography, aortography, bronchography, cholecystography, urography, or venography. VA pathologists will indicate clearly on the SF 515, or SF 503, Medical Record - Autopsy Protocol, which accompanies the case, that microradiographic studies are required. A written report will be sent on each case to the referring VA pathologist and copies of radiographs will be furnished on request.

(5) Crystallographic Studies. VA pathologists desiring special crystallographic studies on surgical or autopsy specimens will contact AFIP for special instructions regarding preservation and shipment of specimens. VA pathologists will indicate clearly on the SF 515 or SF 503 that accompanies the case, that crystallographic studies are required. A written report will be sent on each case to the referring VA pathologist.

(6) Forensic Autopsy Reference Service

(a) The service provided by AFIP may be used in forensic cases involving Federal crimes or where the medical center Director has determined that an autopsy is reasonably required for any necessary purpose of the VA. Forensic cases involving potential violations of State law should be referred to State or local authorities under arrangements between the VA medical center and those authorities which provide them prompt access to, and release of, the deceased patient's body. NOTE: As VA has no authority to perform an autopsy at the request of State or local officials, the service should not be used for or in connection with any case at the request of State authorities. Local district counsel should be consulted to assist in the determination of whether potential Federal or State violations have occurred in connection with any patient's death and, if so, who should undertake responsibility for an autopsy.

(b) To participate in the forensic autopsy reference service, VA pathologists will request general directions from the AFIP. In order that such studies may be beneficial, special precautions are frequently necessary during autopsy prosecution, in collection of material and specimens and in packing and shipping. AFIP will provide a full examination on referred

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autopsy cases including necessary toxicological and other special studies, microscopic examination of tissue, and preparation of a report.

(c) In every instance, VA pathologists will contact the Director, AFIP, before referring a forensic autopsy case. It is strongly advised that such contact be made before the autopsy examination is begun. Telephone contact is encouraged so that there may be early and full discussion. Such exchange should lead to mutually agreeable decisions as to whether or not a case should be referred to AFIP and receipt by the

pathologist of any special instructions for examination, collection, and transmission of material. An officer is on duty at AFIP at night and during weekends who can supply necessary information.

(d) If litigation is likely to occur in connection with a case planned for referral, it is imperative that AFIP be notified by telephone. This contact is essential to ensure proper action such as maintenance of chain of custody of material and evaluation by AFIP legal staff.

(7) Special Studies on Desert Storm Veterans. Arrangements for special studies on Desert Storm Veterans are to be made through VHA Office of Environmental Medicine.

h. The Quarterly VA/AFIP Histopathology Quality Assessment Program. The Quarterly VA/AFIP Histopathology Quality Assessment Program will operate as follows:

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

(2) AFIP will mail in October, January, April, and July each year, four histopathology quality assessment cases. Each case will consist of a representative stained slide together with a brief clinical history. The Chief, Laboratory Service, will ensure examination of each case in the customary manner, which may include any regular local consultation, and return of the consensus diagnosis to AFIP by the date specified for each shipment.

(3) AFIP staff will analyze, for each quality assessment sample, all VA responses and group them in accordance with the submitted diagnoses. A computerized tabular display of the diagnoses will be developed at the AFIP with each VA health care facility identified only by a code number. Each display, together with the AFIP diagnosis, the opinions, when available, of outside recognized authorities, and a critique will be sent to each VA participant approximately 30 days after receipt responses. A copy of the display will be provided to the Director, Pathology and Laboratory Medicine Service (111F), VA Central Office.

(4) Continuing Medical Education (CME) credits will be given to each pathologists who participates. One credit hour for each case reviewed will be assigned for a total of 20 credits in 1 year.

i. The Quarterly Cytopathology Proficiency Testing Program. The Quarterly Cytopathology Proficiency Testing Program will operate as follows:

(1) All Pathology and Laboratory Medicine Service pathologists who review VA cytopathology specimens will participate in the program. Any cytotechnologists will be involved with review of program slides to the extent that they are involved with clinical cytopathology slides.

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(2) Cases for use in the program will be collected from VA medical centers. They will include the full spectrum of specimens and diagnoses seen in the VA medical centers.

(a) Cases will include:

1. Clinical history,

2. Glass slides prepared in the customary manner for cytology specimens, and

3. Discussion of the cytopathological features of the diagnosis.

(b) All cases of malignancy will have histological confirmation of the diagnosis. Non-VA sources may contribute cases to the program.

(3) The program administrators will organize the material and direct the mailing of cases to all participants.

(a) AFIP will mail single slides from four cases to each participating medical center four times each year. Actual mailings will be on a rotating basis to maximize the circulation of slides among the maximum number of participants.

(b) Answer sheets with multiple choice and fill-in questions for each case will be completed independently by each individual pathologist participant.

(c) The case slides will be reviewed in the customary manner, which may include screening by a cytotechnologists, as well as consultations. NOTE: Any markings on slides will be removed prior to remailing to additional medical centers.

(d) Answer sheets will be returned to the program administrators, glass slides will be returned to the AFIP.

(4) If answer sheets are faxed to the program administrators, the data will be integrated along with other participants' answers and a histogram of the answer pattern along with the contributors diagnosis and discussion will be returned by Fax. If mailed, the same material will be returned by mail.

(a) Yearly, each medical center will receive a summary of all participants' answer patterns for each of the cases they had received.

(b) The slides among those received by the medical center which have been identified as proficiency indicators will be identified in this yearly mailing.

(5) Slide specific answer patterns will be accumulated by the program administrators for each case used.

(a) The National Cytopathology Committee will review this data at their annual meeting and identify specific slides which can be used as proficiency indicators.

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(b) The Chiefs of Pathology and Laboratory Medicine Service, will receive reports of the proficiency of each participating pathologists at their medical center.

j. Reporting of Cases Sent to the AFIP. The Chief, Pathology and Laboratory Medicine Service, will ensure that the number of surgicals and consultation cases sent to the AFIP will be recorded appropriately in the workload recording module of the VA medical center's Decentralized Hospital Computer Program (DHCP).

INDEX OF SPECIAL CLINICAL RESOURCE CENTERS (SCRCs)

1. SCRCs have existed in the Veterans Health Administration (VHA) since 1968. A major expansion of this policy to apply to a number of the Department of Veterans Affairs (VA) medical centers capable of providing a wide range of clinical laboratory services that do not involve the transfer of patients from one VA facility to another, was published in 1988.

2. The prime objective in developing SCRCs is to provide a cost effective, efficient network of resources for VA medical centers that do not have access to special clinical laboratory services. VA medical centers should "network" to provide logistical support to send specimens, utilize the Decentralized Hospital Computer Program (DHCP) system and interactive communications systems to send and receive test results.

3. Contrary to past practice, VA medical centers utilizing SCRCs may be charged a fee (at cost) for services provided. A second mechanism for payment from private sector users is through sharing agreements. The choice of utilizing VA SCRCs versus non-VA or military sources for tests, procedures, etc., remains with the VA medical center Director depending on logistics, costs, and turnaround time (TAT) for test results in each VA medical center's locale.

4. Categories or resources, such as immunopathology, are listed in the left hand column as shown in paragraph 5. The right column indicates those VA medical centers offering the resources. VA medical centers in the index are listed alphabetically for ease of location in obtaining details of the tests offered.

5. Index of VA medical centers currently offering special resources (as of date of this chapter):

RESOURCE

AIDS Reference Center
AIDS Testing
Coagulation
Crystal Identification
Cytogenetics

Electron Microscopy, and Immunofluorescence.

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VA MEDICAL CENTER

New York, NY
Lexington, KY
Denver, CO
Milwaukee, WI
Memphis, TN

Albany, NY
Ann Arbor, MI
Atlanta, GA
Boston, MA
Durham, NC
Hines, IL
Houston, TX
Little Rock, AR
Long Beach, CA
Miami, FL
Minneapolis, MN
New York, NY
W. Los Angeles, CA

Flow Cytometry

Albuquerque, MN
Bronx, NY
Denver, CO
Philadelphia, PA

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Cholesterol Standardization and VA
National Clinical Laboratory Standardization Program

Environmental Pathology

Hemoglobinopathies

Immunohistochemical Analysis on Soft Tissue

Immunopathology (and some (DNA) analysis)

Microbiology

Microprobe Analysis

Molecular Biology

Mycology

Mycobacterial diseases including TB

Nerve and Muscle Studies

Radioimmunoassay

Serologic Studies

Special Chemistry (some Endocrine)

Cleveland, OH

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Jackson, MS

Little Rock, AR

Albuquerque, NM

Amarillo, TX

Bronx, NY

Buffalo, NY

Dallas, TX

Durham, NC

Hines, IL

Little Rock, AR

Nashville, TN

New Orleans, LA

New York, NY

Pittsburgh, PA

Portland, OR

Tampa, FL

Denver, CO

Minneapolis, MN

Durham, NC

Minneapolis, MN

Denver, CO

San Antonio, TX

West Haven, CT

Montrose, NY

Bronx, NY

Lexington, KY

Bronx, NY

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Toxicology and Therapeutic Drug Monitoring

Virology

Bronx, NY
Minneapolis, MN

Little Rock, AR
West Haven, CT

March 14, 1994

M-2, Part VI
Chapter 11
APPENDIX 11A

M-2, Part VI
Chapter 11
APPENDIX 11A

March 14, 1994

DEPARTMENT OF VETERANS AFFAIRS (VA)

GUIDELINES FOR DEVELOPING
REQUESTS FOR PROPOSAL (RFP) FOR
REFERENCE LABORATORY TESTING SERVICES

NOTE: These sections are numbered to conform with Office of Acquisition and Materiel Management contracting regulations.

SECTION B

1. Contracting Officer - NOTE: Provides test requirements and quantities; and annual estimated quantities for STAT, extra pickups, and chain of custody services.

2. Offerors shall enter directly on the Test List attached the list price to be billed to the VA for each test. The offeror must provide all data elements for each test included in the proposal (items 1 through 7 listed as follows). Any blank entry shall imply that offeror's laboratory cannot provide that particular test. The responses expected for each test in a proposal are described in the following.

ANNUAL

Schedules for Examination of
SERS Cases at
The Armed Forces Institute of Pathology
Washington, DC 20306-6000

SERS (Systemic External Review of Surgicals)

| Jan | | March | May |
|-------------|-------------|-------------|-------------|
| July | | Sept | Nov |
| <u>SERS</u> | <u>SERS</u> | <u>SERS</u> | <u>SERS</u> |
| <u>SERS</u> | <u>SERS</u> | | |
| GI | | GU | GI |
| GU | | GI | GU |
| Pulmonary | Hematol | Pulmonary | Hematol |
| Pulmonary | Hematol | | |
| Skin | Hepatic | Skin | Hepatic |
| Skin | Hepatic | | |

Submit a total of 18 cases a year.

Legend:

GI = Gastrointestinal
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Hepatic
Pulmonary

| TEST NAME | TAT | ASSAY | ANAL |
|----------------|---------------|---------------|---------------|
| ASSAY | LIMIT | TEST | TEST |
| <u>TIME</u> | <u>METHOD</u> | <u>MAX</u> | <u>SCHED.</u> |
| <u>VOLUME</u> | | <u>(#DAY)</u> | <u>PRICE</u> |
| Analyte, Serum | | (1) | (2) |
| (3) | (4) | (5) | (6) |
| (7) | | | |

(1) = Maximum turn around time (TAT) excluding time required to repeat assay; identify maximum TAT's that exceed those requested by VA with an asterisk(*). For those tests offered on a STAT basis, TAT should be listed separately.

(2) = Give assay schedule - State "MWF" for a test set up Monday, Wednesday, and Friday; "MTWTF" for Monday through Friday, "DAILY", etc.

(3) = Number of days required to complete assay and report a result.

(4) = State assay method.

(5) = Applies to overflow tests only.

(6) = Unit price.

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(7) = Number of patient assays for this test performed in the offeror's testing facility during the last calendar years.

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| GU | | GI | GU |
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SECTION C

DEFINITIONS

STAT Test

Routine Test

Specialized Test

Esoteric Test

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| GU | | GI | GU |
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TAT

Committee

Special handling

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| GI | | GU | GI |
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A test required with a short period of time (8 hours or less) that is specially handled, picked up, tested and reported, within the specified turn-around-time.

A test that is usually performed at high volume in which the result is required in 24 hours generally.

A test that is performed in low volume but the technology, expense, or time-consuming nature of each test, is such that some delay is expected. The delay usually occurs to allow tests received from different centers to be batch to make the operation cost-effective.

A test that is similar to specialized tests, except they can only be done in a few laboratories throughout the country.

The length of elapsed time between pick-up or dispatch of specimen from the contractor's laboratory until the receipt of the completed printed report back in the lab. Exception: For STAT tests, the TAT shall begin at the time of notification by the VA laboratory to the contractor. These definitions apply whether the test is performed by the contractor or a subcontractor.

An individual or group of laboratory directors (Chiefs), or their designees, that evaluate the medical/technical/ service/quality qualifications of offeror's laboratories, and scores these factors in the solicitation. During the life of the contract, this group monitors the quality and service provided by the contractor.

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Unusual circumstances may dictate the need for a specimen to be picked up specially, run out of sequence or at a special time, or reported within a shorter than usual time.

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Overflow

Critical (Panic) Value

Proficiency Testing

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A test usually performed in the VA lab, which might be referred to the contractor's laboratory in case of instrument breakdown or other circumstances interfering with the VA's ability to analyze the specimens.

Those test results that require evaluation by a physician or other health care provider as soon as verified. Failure to take appropriate action as a result of critical value might cause harm to a patient.

An assessment of the accuracy of testing by a laboratory based on the analysis of an unknown specimen analyzed by a large number of other labs. The proficiency survey is conducted by an organization or agency authorized by the Department of Health and Human Services to do so.

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TERMS OF CONTRACT

1. Statement of Work. Contractor shall provide laboratory services to include pickup and transport of specimens to its laboratory; preanalytic processing as defined in its laboratory users manual; analysis, reporting of analytic results, and consultation regarding selection, collection, transportation and result interpretation. The contractor must provide the following services:

a. Provide all necessary supplies, not limited to the following:

- Requisition forms
- Specimen containers
- Dry ice and appropriate container
- Special instructions
- Current list of tests with reference ranges and specimen requirements

b. Provide specimen pick up services as defined in the contract.

c. Transport samples in such a manner as to ensure the integrity of the specimen. Contractor shall supply any special preservatives required for specimen preservation. Frozen specimens shall be shipped on dry ice.

d. Analyze samples.

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e. Routing test results shall be reported within 24 hours of specimen pick-up. STAT test results shall be reported within 8 hours or less of specimen pick-up. Critical Value test results shall be reported immediately.

f. Provide test report summaries by the 20th of each month following the month in which service was delivered.

g. Consult with Laboratory on test results by telephone as needed.

h. Provide Department of Veterans Affairs (VA) Laboratories with a means of communication to permit immediate inquiry regarding the status of pending tests.

2. Licensing and Accreditation

a. Shall have all licenses, permits, accreditation and certificates required by law.

b. Shall be accredited by the College of American Pathologists (CAP).

c. Accreditation by Centers for Prevention and Disease Control (CDC) is required if contractor is engaged in interstate commerce.

d. Laboratory director is a licensed physician or a licensed bioanalyst.

3. Changes. Any proposed subcontractor changes from what is proposed under this contract must have prior approval by the contracting officer. Contractor

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shall be responsible for finding an outside laboratory with appropriate licensure and accreditation to perform tests that the contractor cannot perform. Contractor shall notify laboratory of any change of subcontract laboratory. Any charges shall be submitted to the Contracting Officer Technical Representative (COTR) for review and approval.

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4. Reporting of Results. A report is defined as a printed final copy in triplicate of laboratory testing results. This report shall be received by remote terminal where applicable. If result are telephoned, the report must include the name of the individual notified of the results. Each test report shall at minimum indicate the following information:

- Patient's name and/or identification code (Social Security number)
- Physician's name (if supplied)
- Medical record number (if supplied)
- Facility Name
- Patient's location (clinical/ward), (if supplied)
- Date/time specimen received in Reference Lab
- Test ordered
- Date/time of specimen collection (when available)
- Date test completed
- Test result
- Flag abnormal
- Reference range
- Toxic and/or therapeutic range where applicable
- Testing laboratory specimen number
- Name of testing laboratory (contractor and/or subcontractor)
- Type of specimen
- Any additional comments related to test, provided by submitting labs.
- Any other information the laboratory has that may indicate a questionable validity of test results.
- Unsatisfactory specimen shall be reported with regard to its unsuitability

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for testing.

5. Summaries. Each medical center is to receive the following report by the 20th of each month following the month in which service was delivered: Cumulative (year-to-date) and monthly report of results by ordering physician and by test. The report shall include the turnaround time (TAT) for each test ordered during that month.

6. Quality Control. To ensure proper handling and test performance, the contractor shall provide the following updated information upon request during the life of contract:

a. For quality purposes, tests routinely performed in duplicate should be indicated.

b. Indication of average monthly volume of specified tests in Section B that the laboratory performs.

c. Coefficient of variation of quality control samples of all tests or specified tests the laboratory performs.

d. Proficiency testing data shall include a list of tests outside of the +2SD range for past 2 years. Contractor shall notify laboratory of any test falling outside ± 2SD range during contract period.

e. Contractor shall provide address of processing sites under contract, including subcontracted testing location sites.

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f. Each VA facility will maintain an Internal Quality Control Program to monitor the quality of test results received from the contractor. Unidentified split specimens may

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be sent periodically to the contractor for testing. A split specimen may also be sent to another reference laboratory for comparison. The institutions involved with sending split specimens shall notify the contractor of such specimens only for the purpose of nonpayment. Split specimen testing shall not exceed 1 percent of the total annual test volume and shall be processed free of charge by the contractor.

g. The contractor(s) facilities, methodologies (defined as the principal of the method and the references), and quality control procedures may be examined by representatives of the VA at any time during the life of the contract.

7. Service

a. The contractor shall provide telephone number(s) and contact person to be used by the participating facilities to make specimen problem inquiries and problem solving at all times including weekends and holidays.

NOTE: Also include names and telephone numbers of technical Directors and Pathologists available for consultation.

b. Contractor agrees to maintain the minimum acceptable service, reporting systems and quality control as specified herein. Immediate (within 24 hours) notification must be given to VA upon adverse action by a regulatory agency.

c. Contractor shall submit with this proposal a percentage discount off the specified published price list for all tests other than those detailed in

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Section B. Any new tests or tests sent to a subcontractor should be covered under the discounts.

d. Contractor shall assign a specific local account representative to each facility.

e. Contractor shall advise facility of any changes in methodology, procedure, reference ranges and any new tests introduced.

In the event that the contractor changes the assay procedure or a critically important component of an assay (e.g., and antibody, purified antigen, etc.), the contractor shall notify the contracting office and the laboratory director(s) prior to the intended change and provide documentation that the quality and efficacy of the test will remain unchanged or be improved. Changes in the assay materials or procedure may be sufficient cause for changing to an alternate contractor for the assay(s) for the duration of the contract at the sole discretion of the Contracting Officer. The contractor is liable for excess procurement costs.

8. Telecommunications

a. Telecommunications Linkage. Each hospital shall receive, where applicable, transmission of the results to a teleprinter located at the hospital site. Contractors shall provide personal computers (PC) or teleprinters at no charge for this service. Any necessary "hooks-ups" shall be the responsibility of the contractor. The transmission of all the completed and/or partial test results shall arrive at the hospital within

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published TAT except where specified. The contractor is responsible for all supplies required for transmission of test results.

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b. The teleprinter system (all elements of the transmission path including the transmitter and associated receivers) must be able to:

(1) Print multipart copies of the laboratory reports, minimum of three copies.

(2) Provide format of the copies equal to the current facilities format or acceptable to the Laboratory Advisory Committee.

(3) Provide remote teleprinter motor on and off.

(4) Operate in a "normal" medical center operating environment without additional expense for air conditioning, humidity control, or noise suppression.

(5) Reprint a report at the local laboratory.

c. The contractor shall:

(1) Be responsible for preventive and as-needed maintenance on the teleprinter, PC and all associated devices;

(2) Have the responsibility to train medical center personnel in routine operations (loading and unloading paper, ribbon changes, test and reset); and

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(3) Provide a validation service (fax or telephone) in the event of transmission or printer degradation.

9. Testing Methodology. Testing methodology for a test must be defined in the laboratory users manual.

10. Bench Mark Reference. VA may submit, as part of the proposal evaluation process, a number of specimens for analysis as a bench mark reference. These tests shall be performed and reported without charge to VA.

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Legend:

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GU = Genitourinary

Hematol = Hematologic/Lymphatic

Hepatic

Pulmonary

SECTION D

Sample Preparation: Each participation VA facility
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| Jan July | | March Sept | May Nov |
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| <u>SERS</u> | <u>SERS</u> | <u>SERS</u> | <u>SERS</u> |
| <u>SERS</u> | <u>SERS</u> | | |
| GI | | GU | GI |
| GU | | GI | GU |
| Pulmonary | Hematol | Pulmonary | Hematol |
| Pulmonary | Hematol | | |
| Skin | Hepatic | Skin | Hepatic |
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| <u>SERS</u> | <u>SERS</u> | | |
| GI | | GU | GI |
| GU | | GI | GU |
| Pulmonary | Hematol | Pulmonary | Hematol |
| Pulmonary | Hematol | | |
| Skin | Hepatic | Skin | Hepatic |
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| <u>SERS</u> | <u>SERS</u> | | |
| GI | | GU | GI |
| GU | | GI | GU |
| Pulmonary | Hematol | Pulmonary | Hematol |
| Pulmonary | Hematol | | |
| Skin | Hepatic | Skin | Hepatic |
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| GI | | GU | GI |
| GU | | GI | GU |
| Pulmonary | Hematol | Pulmonary | Hematol |
| Pulmonary | Hematol | | |
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| <u>SERS</u> | <u>SERS</u> | | |
| GI | | GU | GI |
| GU | | GI | GU |
| Pulmonary | Hematol | Pulmonary | Hematol |
| Pulmonary | Hematol | | |
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| GI | | GU | GI |
| GU | | GI | GU |
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| Pulmonary | Hematol | | |
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| GI | | GU | GI |
| GU | | GI | GU |
| Pulmonary | Hematol | Pulmonary | Hematol |
| Pulmonary | Hematol | | |
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| GI | | GU | GI |
| GU | | GI | GU |
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| GI | | GU | GI |
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| GI | | GU | GI |
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| Pulmonary | Hematol | Pulmonary | Hematol |
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Contracting Officer Note: The specifications should include the requirements for shipping frozen specimens on dry ice and indicate who is responsible for packaging the specimens.

Contracting Officer Note: Specify responsibility for packaging.

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| GI | | GU | GI |
| GU | | GI | GU |
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SECTION F

DELIVERIES OR PERFORMANCE

SPECIMEN PICKUP AND REPORTS

1. Pick-Up Schedule. Contractor(s) shall provide routinely scheduled pick-up of test specimens from each hospital 7 days a week if required, at no charge. NOTE: Contracting Officer may change this requirement to less than 7 days. Contractors and VA shall have an agreement as to nonpick-up holidays. The precise hours of pick-up shall be determine separately with each hospital and may be adjusted any time during the terms of the contract based on the frequency and volume demand of each hospital. Prices as set forth in Section B are based on one pick-up per day. Any extra pick-up or STAT pick-ups needed must be available.

2. Reports of test results generally shall be received within 24 hours following specimen pick-up. The submitting laboratory recognizes that certain test procedures shall require a longer turnaround time (TAT) than 24 hours. The contractor is required to provide a list of those tests that routinely have a TAT in excess of 24 hours. Test results shall be received no later than 12 hours after completion of test.

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| <u>SERS</u> | <u>SERS</u> | | |
| GI | | GU | GI |
| GU | | GI | GU |
| Pulmonary | Hematol | Pulmonary | Hematol |
| Pulmonary | Hematol | | |
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a. STAT test results must be printed, where applicable, at the VA laboratory within the TAT specified for stat tests.

b. Critical Value Test Results shall be reported by telephone to the laboratory as soon as verified and shall be printed at those VA laboratories having remote printers linked to the contractor's computer. Critical value test reports shall include documentation of the person notified at the sending laboratory, the date and time of notification, and name of person at contract laboratory notifying the sending laboratory.

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| GI | | GU | GI |
| GU | | GI | GU |
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SECTION L

INSTRUCTIONS, CONDITIONS, AND NOTICES

PROPOSAL FORMAT AND EVALUATION OF PROPOSALS

In order that each offeror's proposal be properly evaluated, it is necessary that each offeror succinctly respond to all items in the same order as presented herein.

Offers shall be organized and bound in one, or more, volumes with sections appropriately identified.

A. Cover Letter. Section 1 shall be a maximum two-page "Cover Letter" and introduction, and shall include the name and address of the organization submitting the proposal, together with the name, address, and telephone number of the contact person, who has the actual power to bind and make representations relative to the proposal and any resultant contract, for the organization.

B. Table of Contents. Section 2 shall be a detailed "Table of Contents" and shall include an outline of the proposal, identified by sequential page number and by section reference number and section title.

C. Certification. Each offeror shall submit all required certifications with the proposal, including:

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| GI | | GU | GI |
| GU | | GI | GU |
| Pulmonary | Hematol | Pulmonary | Hematol |
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1. Federal Clinical Laboratory License Number,
2. Medicare Supplier Code Number,
3. Medicaid Certificate Number,
4. List of professional staff and their respective curriculum vitae (CV),
5. Any additional applicable licensing,
6. NIDA Certification for Toxicology, and
7. College of American Pathologists (CAP) Accreditation Number.

D. Accreditations. Photocopies of any facility accreditation held by offeror and offeror's current applicable state licensing and/or Center for Prevention and Disease Control (CDC) accreditation or proof that such documents are being processed must be furnished by the offeror.

E. Organization. Proposals shall be organized, documented, and bound in one or more volumes with sections appropriately identified.

F. Chain of Custody. Offerors shall submit a copy of protocol for chain of custody for toxicology specimens and indicate any additional costs to utilize this service.

G. Qualified Proposal. Offerors of a "qualified proposal" may be subjected to an on site inspection of their laboratory facilities by a member, or members, of the Evaluation Committee, to verify information as claimed in the offeror's written proposal and to further determine, upon such site inspection, if any adjustment to the offeror's final score shall be required.

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| GU | GI | GU |
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H. Laboratory Testing Manual. Offerors submit a Laboratory Testing Manual containing at a minimum the following information:

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| Jan July | | March Sept | May Nov |
|-------------|-------------|---------------|-------------|
| <u>SERS</u> | <u>SERS</u> | <u>SERS</u> | <u>SERS</u> |
| <u>SERS</u> | <u>SERS</u> | | |
| GI | | GU | GI |
| GU | | GI | GU |
| Pulmonary | Hematol | Pulmonary | Hematol |
| Pulmonary | Hematol | | |
| Skin | Hepatic | Skin | Hepatic |
| Skin | Hepatic | | |

Submit a total of 18 cases a year.

Legend:

GI = Gastrointestinal

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Hematol = Hematologic/Lymphatic

Hepatic

Pulmonary

GENERAL SERVICES

Department Hours of Operation
 Accreditation
 Technical Staff
 Marketing, Courier Service, and Client Service Departments (Method of Contacting,
 Phone Numbers, Hours of Availability)
 Quality Assurance Information
 Billing Procedures
 Additional Services
 Toxicology Services
 Procedures and criteria for phoning reports and other important information
 Requisition Forms
 Report Forms

SPECIMEN COLLECTION (where applicable)

Blood Collection
 Urine Collection
 Clean Catch Urine Collection Procedure
 24 Hour Urine Collection Procedure
 Stool Collection
 Synovial Fluid Collection
 Semen Collection
 Cytology

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| <u>SERS</u> | <u>SERS</u> | | |
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| GU | | GI | GU |
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| Pulmonary | Hematol | | |
| Skin | Hepatic | Skin | Hepatic |
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SPECIMEN HANDLING. General information concerning packaging and pickup of transport of specimens.

PROFILES AVAILABLE AND THEIR COMPOSITION

ALPHABETICAL LISTING OF TESTS

FEE SCHEDULE

FOR EACH TEST:

- Test name
- Price
- Cost Per Test (CPT) Code Number
- Specimen Requirements including specimen integrity, specimen, stability, patient preparation and/or physiologic and/or drug interferences, dietary restrictions, fasting conditions (if applicable)
- Turnaround Time (TAT) and Days Performed
- Methodology (with reference if requested) and instrument used
- Normal test values (Male/Female/Age)
- Toxic and Therapeutic Ranges, (if applicable)
- Comments (if applicable)

I. The content of the proposal must adhere to the following form:

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| GI | | GU | GI |
| GU | | GI | GU |
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| Pulmonary | Hematol | | |
| Skin | Hepatic | Skin | Hepatic |
| Skin | Hepatic | | |

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- Pulmonary

1. Offeror's Capabilities

This section shall be entitled "Offeror's Capabilities" and must include a description of offeror firm's resources, experience, capabilities, and relevant information regarding organization stability and strength as listed:

- a. Background,
- b. Experience,
- c. Local customer references (three or more),
- d. Address and telephone number of main office and local offices, and
- e. List of subcontractors.

2. Test Methodology

This section shall be entitled "Test Methodology" and shall include a response to the following test list requirements:

- a. Offeror's response to the tests listed in Section B shall state the method of analysis for each test in the proposed test for this exhibit.
- b. In responding to the list of tests in Section B, the offeror shall state the method of analysis for each test in the proposed test list for this exhibit. The offeror shall be prepared to provide on request information such

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| <u>SERS</u> | <u>SERS</u> | | |
| GI | | GU | GI |
| GU | | GI | GU |
| Pulmonary | Hematol | Pulmonary | Hematol |
| Pulmonary | Hematol | | |
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as listed below regarding tests proposed for inclusion in these test lists (CO NOTE: Include if information is desired):

(1) Documentation of the quality of assays by providing information on technical sensitivity, specificity, and precision as well as on-going Quality Control Program for assays;

(2) Provide detailed descriptions of procedures for assays from laboratory procedure manuals for evaluation and review, including equipment used;

(3) Describe the mechanism for ensurance of consistent quality of assay materials (e.g., antibodies, purified antigens and standards for immunoassays) throughout the duration of the contract;

(4) Document the clinical efficacy of assays in distinguishing disease states (the offeror shall provide, on request, information as may be needed to evaluate the nature of the proposal on clinical sensitivity, clinical specificity, predictive values of positive and negative test results, as information on methodology, and studies performed to determine these values).

3. Specimen Handling and Pick-up Procedure

This section shall be entitled "Specimen Handling and Pick-up Procedures" and shall address the following requirements:

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| GI | | GU | GI |
| GU | | GI | GU |
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| Pulmonary | Hematol | | |
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a. Provide a proposed schedule of pick-up times for each service location for weekends and holidays if this schedule differs from that shown in Section B (see pg. 11C-1).

b. Provide a description of the mechanism for pick-up of STAT specimens and an estimate of the probable elapsed time from notification of a STAT specimen for pic-up to the time the STAT specimen is picked-up for each service location.

4. Quality Control

a. This Section shall be entitled "Quality Control" and shall include the following information:

b. Detailed description of quality control procedures as specified in Section C (see pg. 11C-2) that are used in the offeror's laboratory.

5. Reporting Protocols

This section shall be entitled "Reporting Protocols" and shall address the following:

a. Describe how the offeror will provide reports, including equipment to be installed at each VA service location, computer facilities available at the offeror's site, communications methods, requirements for additional telephone lines, any provision for back-up reporting in case of failure of the offeror's

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host computer or failure of the terminals and/or printers installed at VA sites.

b. State the proposed frequency of printing test results at each VA service location if the VA request for on-demand printing cannot be met.

c. Describe in detail the format of the test result report to be used and provide a mock up of the proposed test report format.

d. Describe protocol for reporting Critical Value Test Results.

e. Describe protocol for reporting STAT test results.

f. The offeror shall provide statements regarding proposed discounts and added charges to be applied to list prices. The information shall be provided under the following headings:

(1) Discount for more than one test on a single specimen.

(2) Discount to be applied to prospective offeror's currently published commercial Fee Schedule.

(3) Added charges for emergency (STAT) services. This information shall be used by VA to complete the evaluation of the Test List and Fee Schedule.

(4) Added charges for additional routine (non-STAT) pickups.

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| Pulmonary | Hematol | | |
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(5) Charges for processing chain of custody services for toxicology specimens.

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| GU | | GI | GU |
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| Skin | Hepatic | | |

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g. For all tests shown on the offeror's Test List(s) the offeror shall state a TAT for each test including those tests for which the VA has not specified a TAT time in Section B; and for those tests available to the TAT expected for routine test performance, excluding instances requiring repeat analysis for whatever reason. Similarly, in responding to the portions of the Exhibit Test list headed "STAT Test Requirements" and "Overflow Test Requirements", the proposal shall state a TAT for each test included in the proposal, since it is expected that a turnaround time for a STAT test shall be shorter than for a routine test and that TATs for tests listed under "Overflow Test Requirements" may be related to the number of tests sent at a given time. Each proposed turnaround time exceeding the TAT requested by VA in the list of tests in Section B shall be identified with an asterisk (*).

The offer shall include a schedule of test performance showing days of the week when each test included in the proposal is set up and the analytical time (number of days required to complete the analysis and report a result).

The TAT for each test must be listed in the laboratory manual. The submitting VA laboratory shall be notified for any test that shall not be completed within the published TAT and about any unacceptable specimen within 12 hours of a problem being identified.

h. In responding to the "Overflow Test Requirements", the offeror shall state the maximum workloads (number of tests) it is able to accept per day as overflow tests.

i. Offeror must compute and report the following information:

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(1) The total number of entries made by offeror in the "Unit Price" column of the Tests List.

(2) The percentage of those entries to the total number of test types in the complete Test List provided by VA.

(3) The percent of proposed TATs that meet the TATs specified by VA.

(4) The format for this report shall be a chart as follows:

| <u>CRITERIA</u> | <u>EXHIBITS</u> <u>B, C, D, E, (ETC.)</u> |
|---------------------------------------|--|
| TEST TYPES _____ | |
| PERCENT OF TEST TYPES _____ | |
| TURNAROUND TIMES _____ | |
| PERCENT OF TURNAROUND TIMES MET _____ | |

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(5) Percentage of quantity of tests listed in solicitation that are included in proposal.

(6) Operational System, including the merits of:

- (a) General management policies and procedures.
- (b) Methods for testing and reporting of test results.
- (c) Specimen handling policies and procedures.
- (d) Equipment maintenance policies and procedures.
- (e) Information and data handling policies and procedures.

(f) Printing of reports via computer or printer in the VA laboratory (printer provided by offeror).

j. Results of VA Inspection and Various Verification Procedures, Including:

- (1) Inspection of laboratory, personnel, facilities, and testing techniques
- (2) Results of processing unknown specimens

k. Cost:

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The lowest evaluated price in Section B will be given the maximum points available for cost evaluation purposes. All others will receive a percentage of the points available for evaluation based on the relationship of their cost to the lowest cost.

$$\frac{\text{Offeror's Score}}{\text{Offeror's Cost}} = \frac{\text{Lowest Offered Cost}}{\text{XMaximum points available}}$$

(see Federal Acquisition Regulation (FAR) 52.215-16 Contract Award)

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SECTION M

EVALUATION FACTORS FOR AWARD

I. Method of Award

The contract award shall be based on scoring system recognizing service and quality offered for the core group of tests included in this proposal.

II. Cumulative Score Rating Evaluation Criteria

The Proposal shall be rated according to specific criteria on the basis of an assigned-point system.

In evaluating the proposal, each Department of Veterans Affairs (VA) medical will determine its own specific weight to include:

A. Resources Required

1. Personnel capability sufficient to provide for personnel turnover during period of the contract.
2. Equipment capability to successfully meet those VA needs for which the contract is to provide. (Both laboratory and data handling equipment).
3. Fiscal capability and company stability to successfully comply with contract requirements.

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B. Quality Assurance Systems

Offeror must have control systems adequate to ensure satisfactory service performance under the contract. Special attention by the evaluators shall be given to quality control methods employed by offeror.

C. Services Available Including:

1. Ability to provide services with turnaround times (TATs) that satisfy the clinical requirements for patient care. While the offeror purpose turning times that are faster than those stated by the offeror's ability to provide TATs for services required by VA shall be evaluated in scoring a proposal. This evaluation of TATs shall be based on the maximum turnaround times stated and on the test schedule showing days of the week when each test included in the proposal is set up and the analytical time (number of days required to complete the analysis and report a result).

2. Published commercial fee schedule, with discounts offered, which can expand VA's options to obtain a wider variety of test services, if necessary.

3. Emergency (STAT) service capability.

4. Percentage of test types listed in solicitation that are included in proposal.

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