CHAPTER 240: VETERANS HEALTH ADMINISTRATION – PATHOLOGY AND LABORATORY MEDICINE SERVICE

1 PURPOSE AND SCOPE

This document outlines the space planning criteria for Chapter 240: Pathology and Laboratory Medicine Service. It applies to all medical facilities at the Department of Veterans Affairs (VA).

Department of Veterans Affairs (VA) medical center Laboratory Service provides a wide range of clinical and anatomic pathology services which are necessary to carry out tests and procedures for diagnostic use in patient care.

The Department of Veterans Affairs (VA) Outpatient Clinics provide limited clinical laboratory services based on the need to screen for or monitor a disease process or to determine the need for hospitalization. Space Criteria for Outpatient Clinics are identified in Chapter 265. Specimens for more complex tests are collected, processed and forwarded to medical center laboratories for performance of the tests.

2 DEFINITIONS

A. Affiliated: An arrangement whereby a school of medicine agrees to partially staff a VA facility with faculty physicians, residents and interns. In return, the VA provides the medical school with a venue to train new physicians. In this arrangement, the VA retains responsibility for the care of its patients while the school of medicine retains responsibility for all graduate level education and training.

B. Anatomical Pathology: The branch of pathology dealing with the examination of tissue removed from the patient during surgery or an outpatient procedure. Anatomic pathology may include, but not limited to histology, cytology and autopsy. A frozen section laboratory is a subset of the histology Laboratory and is located in histology or for hospitals with a large volume of frozen sections in the surgical suite. Morgue operations are generally housed in a non-public area accessible to service vehicles.

C. Automated Lab: A central area in the clinical laboratory that performs the high-volume, automated testing of hematology, coagulation, chemistry and urinalysis.

D. Blood Bank: An organization that collects, processes, and stores blood and blood products for future use in transfusions and for other purposes.

E. Chemistry: Consisting of general and automated chemistry, urinalysis, toxicology, and other special chemistry studies that detect or measure levels of elements, enzymes, hormones, vitamins, drugs, etc. within body fluids.

F. Clinical Pathology: The branch of Pathology dealing with the examination and laboratory study of fluids (e.g. Blood) and other non-tissue specimens from patients. Among the many branches of clinical pathology are Chemistry, Hematology, Microbiology, Serology, Immunology, Urinalysis, and others.

G. Coagulation: The section of the clinical laboratory that tests blood clotting capabilities; typically combined with hematology or the automated lab in most laboratories.

H. Concept of Operations: A user-developed guide to the functional operation of the VA healthcare facility. It defines the function of the facility and the scope of medical or pathology services to be provided in the new or remodeled space.

I. Cytology: The section of the clinical laboratory that studies cells for morphologic abnormalities indicative of disease.

J. Frozen section: Part of histology, an area that performs immediate gross and microscopic evaluation of surgical specimens achieved by freezing the tissue, making a thin slice of a specimen, and studying that specimen under a microscope. The frozen section area is typically located within histology but is sometimes in the surgical suite.

K. Full-Time Equivalent (FTE): A staffing parameter equal to the amount of time assigned to one full time employee. It may be composed of several part-time employees whose total time commitment equals that of a full-time employee. One FTE equals a 40 hours per week.

L. Gross pathology/tissue: The recognition of disease based on naked-eye examination of surgical specimens or at autopsy. The physical exam of a large specimen of body tissue to evaluate its conditions and the presence of disease.

M. Hematology: The section of the clinical laboratory for the testing of blood samples. Includes manual, automated, and special hematology, serology, and coagulation (process of turning a liquid into a solid, especially blood clotting) to determine cell types, population counts, etc.

N. Histology: The section of anatomic pathology that study of normal and diseased tissue by embedding them in paraffin blocks and then prepares slides from thin slices of the blocks. The slides are stained and then studied under a microscope. The blocks and slides must be stored for up to twenty five years.

O. Immunology: The section of clinical pathology that studies the immune system's stimulation by antigens.

P. Input Data Statement: A set of questions designed to elicit information about the healthcare project in order to create a Program for Design (PFD) based on the criteria parameters set forth in this document. Input Data Statements could be Mission related, based in the project's Concept of Operations; and Workload or Staffing related, based on projections and data provided by the VHA or the VISN about the estimated model of operation. This information is processed through mathematical and logical operations in VA-SEPS.

Q. Laboratory Information System (LIS): The laboratory's computer system and software. The LIS keeps track of all orders, specimens, quality control, and test

results. It is typically interfaced with the hospitals information system and all automated lab equipment.

R. Manual Laboratory: A section of the clinical laboratory that performs manual testing in chemistry, hematology, coagulation, and urinalysis. It is usually located peripherally to the automated lab.

S. Microbiology: The section of the clinical laboratory that may test for microorganisms including bacteria, viruses (virology), parasites (parasitology), fungi and fungus disease (mycology) and tuberculosis, along with other special organism studies related to the identification and quantification of organisms.

T. Molecular Pathology: An esoteric section of the clinical laboratory that uses specialized techniques to evaluate disease at the molecular level.

U. Morgue: A area specifically arranged and equipped for the study and storage of human remains. A morgue may or may not include an autopsy facility.

V. Mycology: Part of microbiology, the area where specimens are tested for the presences of fungus.

W. Net-to-department gross factor (NTDG): This number, when multiplied by the programmed net square foot (NSF) area, determines the departmental gross square feet (DGSF) The NTDG factor adopted for Pathology and Laboratory Medicine is **1.40**.

X. Office / Cubicle: A private office is an enclosed room outfitted with either standard furniture or system furniture. An administrated cubicle is within an open room and is constructed out of system furniture.

Y. Point of Care Testing (POCT): Diagnostic clinical laboratory testing performed at or near the site of patient care rather than within the central laboratory. POCT mainly uses hand held or small instruments for immediate testing at the patient's bedside or outpatient location. Workspace is required in the central laboratory for quality assurance and monitoring of POCT and filing of maintenance records.

Z. Program for Design (PFD): A space program based on criteria set forth in this document and specific information about Concept of Operations, workload projections and staffing levels authorized.

AA. Reference or Referral Laboratory: A Laboratory that performs tests sent from outside entities. Reference labs are used by laboratories that do not have the instrumentation or capability to perform a specific test.

BB. Room Efficiency Factor: A factor that provides flexibility in the utilization of a room to account for patient delays, scheduling conflicts, and equipment maintenance. Common factors are in the 80 to 85% range. A room with 80% room efficiency provides a buffer to assume that this room would be available 20% of the time beyond the planned operational practices of the room. This factor may be adjusted

based on the actual and/or anticipated operations and processes of the room / department.

CC. SEPS (VA-SEPS): Acronym for Space and Equipment Planning System, a digital tool developed by the Department of Defense (DoD) and the Department of Veterans Affairs to generate a Program for Design (PFD) and an Equipment List for a VA healthcare project based on specific information entered in response to Input Data Questions. VA-SEPS incorporates the propositions set forth in this chapter as well as all chapters in VA's Handbook 7610. VA-SEPS has been designed to aid healthcare planners in creating a space plan based on a standardized set of criteria parameters.

DD. Serology: A section of the clinical laboratory that performs immunology tests. Serology is usually not a stand alone section; it could be located in several sections of clinical pathology.

EE. Specimen Processing (Accessioning): The receiving, verifying, logging, and preparing of specimens for distribution to the appropriate testing area in the laboratory.

FF. Urinalysis: A section of the clinical laboratory where urine analysis is performed. This area is usually located in the chemistry area.

GG. Virology: Typically a part of microbiology where specimens are tested for the presence of viruses.

3 OPERATING RATIONALE AND BASIS OF CRITERIA

A. Laboratory space allocation must be based on multiple criteria. Factors to be considered would include overall laboratory workload [reflected in data reported in the Laboratory Management Index Program (LMIP)], the number of FTE assigned to the lab, the Medical Complexity Grouping (MCG) of the facility in which the Laboratory will be located, and the variety and complexity of services to be offered by the laboratory. All of these factors should be used to assess and determine the space needs of the Pathology and Laboratory Medicine Service with respect to a given facility. No single factor is predominant over the others. Rather it is more relevant to compose a composite profile of the proposed laboratory using all available data.

B. For planning purposes, the proposed laboratory can be projected into one of four (4) "Levels". As stated, the assignment of a "Level" to a proposed laboratory must be based on the assessment of multiple factors. No single factor is predominant. The following laboratory level categories are used in this document in order to allocate space:

1. Level S (small): Annual LMIP workload of < 250,000 tests, facility MCG of 3, less than 20 Laboratory FTEs, basic chemistry, hematology, microbiology, etc. services performed

2. Level M (medium): Annual LMIP workload of 250,000 to 500,000 tests, facility MCG of 2, 20 to 40 Laboratory FTEs, more advanced chemistry, hematology, microbiology, and other clinical laboratory services performed

3. Level L (large): Annual LMIP workload of 500,000 to 1.5 million tests, facility MCG of 1c or 1b, greater than 40 Laboratory FTE, advanced and complex chemistry, hematology, microbiology, and other clinical laboratory services performed. May provide specialized and reference laboratory services to other VA Medical Centers and the community.

4. Level VL (very large): Annual LMIP workload of greater than 1.5 million tests, facility MCG of 1b or 1a, greater than 40 Laboratory FTE, advanced and complex chemistry, hematology, microbiology, and other clinical laboratory services performed. May provide specialized and reference laboratory services to other VA Medical Centers and the community.

C. In the design of a clinical laboratory, a determination of the required square footage is only the beginning. The use of average figures for all laboratories is misleading, tends to perpetuate existing designs and to prevent innovation. The use of average figures is not a form of laboratory planning, but rather is something that is done instead of planning-intended primarily to provide a basis for estimating construction costs. The criteria for each laboratory section are intended to provide flexibility so that space will be planned based on the need to respond to the medical center's patient care programs. The number of square feet (meters) for each laboratory section are considered adequate for normal operations, but may be modified during program and conceptual development if adequately justified.

D. Any deviations from criteria should be discussed among, and concurred in by VHA (including CM) and the Office of the Controller, as these changes may have design and budgetary impact.

E. The following factors concerning space determinations should be taken into consideration:

1. The instrumentation required to perform the test menu in the laboratory, and the degree of automation, is the key driver of space. In the automated lab, a very large volume of tests can be performed on one analyzer run by one staff member — test volume and staffing are not generally used to determine the amount of space required for Laboratory operations in automated areas. The degree of automation has a significant impact on both the space and configuration of the laboratory. One new automated instrument often consolidates several manual workstations or individual instruments. Automation is taking tremendous strides — every year; more tests are available on automated analyzers, reducing the number of staff needed in technical areas and giving laboratories the capability to perform esoteric tests that they could not provide in the past.

2. In highly manual areas, where automation is not yet developed, there is more correlation between test volume, staffing, and space. These areas include histology, microbiology, and the blood bank. Even in these areas, new technology is being developed to automate specific processes — within the next

five to ten years; additional automation will change the facility requirements for these Laboratory sections as well. This document assumes for planning purposes that automation will not require any of these areas to be larger than they are currently.

3. Laboratory work area space for medium and larger laboratories includes space for the Department of Veterans Affairs (VA) and non-the Department of Veterans Affairs (VA) medical technology student/pathology resident training.

4. Laboratory work area space for all VA laboratories includes refrigerated and non-refrigerated storage space for several days' supply of reagents, control, stains, diagnostic instruments supplies (cups, trays, tubing, etc.), glassware and other supplies (microscope slides, disposable pipettes, etc.).

4 PROGRAM DATA REQUIRED (Input Data Questions)

A. Mission Input Data Statements

1. Is an S Level Laboratory authorized? (M)
2. Is an M Level Laboratory authorized? (M)
3. Is an L Level Laboratory authorized? (M)
4. Is a VL Level Laboratory authorized? (M)
5. Is a Satellite Specimen Collection Area authorized? (M)
6. Is a Mass Spectrometer authorized? (M)
7. Is Cytogenetics authorized? (M)
8. Is a Hemotherapeutics Blood Bank Room authorized? (M)
9. Is a Blood Bank Donor Room authorized? (M)
10. Is a Microbiology Mycobacteriology Laboratory authorized? (M)
11. Is a Microbiology Mycology Laboratory authorized? (M)
12. Is Molecular Testing authorized? (M)
    a. Are molecular methods to be utilized requiring photographic development authorized? (M)
    b. How many Molecular Testing Technician / Technologist FTE positions are authorized? (S)
13. Are Anatomical Pathology Work Areas authorized? (M)
    a. Is Surgery Service authorized? (M)
    b. How many Anatomical Pathology Technician / Technologist FTE positions are authorized? (S)
14. Is an Electron Microscopy Suite authorized? (M)
    a. Is a Finishing Room for the Electron Microscopy Suite authorized? (M)
    b. How many Electron Microscopy Technician / Technologist FTE positions are authorized? (S)
15. Is an Autopsy Suite authorized? (M)
16. Is a Pathology Residency Program authorized? (M)
    a. Is a Library for the Residency Program authorized? (M)
    b. Is a Classroom / Laboratory for the Residency Program authorized? (M)
    c. How many Pathology Resident FTE positions are authorized? (S)
    d. How many Education Coordinator FTE positions are authorized? (S)
    e. How many Student FTE positions are authorized? (S)
    f.

B. Workload Input Data Statements
1. How many daily blood specimen collections are projected? (W)
2. How many daily urine specimen collections are projected? (W)
3. How many annual deaths are projected? (W)

C. Staffing Input Data Statements
1. How many Clinical Pathology Technician / Technologist FTE positions are authorized? (S)
2. How many Staff Pathologist FTE positions are authorized? (S)
3. How many Pathology and Laboratory Medicine Service Section Chief FTE positions are authorized? (S)
4. How many Clerical FTE positions are authorized? (S)
5. How many Administrative Assistant FTE positions are authorized? (S)
6. How many Chief Medical Technologist FTE positions are authorized? (S)
7. How many Clinical Laboratory Scientist FTE positions are authorized? (S)

D. Miscellaneous Input Data Statements
1. How many FTEs will work on peak shift? (Misc)
2. How many FTE positions are not authorized to have office or cubicle space? (Misc)

5 SPACE CRITERIA – MEDICAL CENTER LABORATORY

A. Patient Specimen Collection Area:

1. **Waiting (WRC01) ..... 120 NSF (11.2 NSM)**
Minimum NSF if number of projected daily blood specimen collections is between twenty five and one hundred and fifty; provide an additional 55 NSF for each increment of fifty projected daily blood specimen collections greater than one hundred and fifty.

   An additional 55 NSF allocates 25 NSF for one accessible seat and 30 NSF for two standard seats.

2. **Reception (RECP1) ..... 40 NSF (3.7 NSM)**
Provide one per Patient Specimen Collection Area; provide two if a Satellite Specimen Collection Area is authorized.

3. **Blood Specimen Collection Room (LBBD1) ..... 150 NSF (11.2 NSM)**
Minimum NSF if number of projected daily blood specimen collections is between twenty five and one hundred and fifty; provide an additional 50 NSF for each increment of fifty projected daily blood specimen collections greater than one hundred and fifty.

4. **Toilet, Urine Specimen Collection (TLTU1) ..... 50 NSF (4.7 NSM)**
Provide one if number of projected daily blood specimen collections is between twenty five and fifty; provide an additional one for each increment of fifty projected daily urine specimen collections greater than fifty.

   This area must be immediately adjacent to the Blood Specimen Collection Room so that technical staff can rapidly attend to needs of patients who need

assistance. Locks should not be placed on these doors and an emergency call system must be installed for patient use.

B. Core Laboratory Work Areas:

1. **Specimen Accessioning, Processing and Distribution Room (LBBD2) .....350 NSF (32.6 NSM)**
Minimum NSF if Level S Laboratory is authorized; provide an additional 50 NSF if Level M Laboratory is authorized; provide an additional 250 NSF if Level L Laboratory is authorized; provide an additional 350 NSF if Level VL Laboratory is authorized.

   This is a central receiving point for all specimens and requests, except those for histology, cytology, and microbiology which are delivered directly to those sections. If a Pneumatic Tube system is approved one station should be located in this area. Specimens, with accompanying request forms, are examined, centrifuged if necessary, and routed to the various sections of the laboratory. All specimens are potentially dangerous, and centrifugation should be performed under a hood, or the ventilation system should be designed in a manner which will prevent dispersion of dangerous aerosols into the environment.

2. **Automated Data Processing, Control Area (XXYYC).....120 NSF (11.2 NSM)**
Provide one per Core Laboratory Work Area.

   This is an area for computers, printers and immediate ADP data storage for retrieval of results, quality control data and patient demographic information. It is also critical to generating work lists away from the highly contaminated specimen processing area.

3. **Automated Data Processing, Processor Area (XXYYC) .....50 NSF (4.7 NSM)**
Provide one per Core Laboratory Work Area.

   This space accommodates the hardware used to connect laboratory instrumentation on-line with the medical center central processing unit.

C. Clinical Pathology Work Areas:

1. **Clinical Chemistry (LMCH3) .....500 NSF (46.5 NSM)**
Minimum NSF if Level S Laboratory is authorized; provide an additional 500 NSF if Level M Laboratory is authorized; provide an additional 1,600 NSF if Level L Laboratory is authorized; provide an additional 2,000 NSF if Level VL Laboratory is authorized.

   In this area technical personnel use automated, semi-automated and manual instrumentation to perform basic chemical analyses common to all levels of laboratories.

2. **Chemistry, Special Chemistry (LMCH4) .....580 NSF (53.9 NSM)**
Minimum NSF if Level M Laboratory is authorized; provide an additional 320 NSF if Level L Laboratory is authorized and an additional 150 NSF if a Mass

Spectrometer is authorized; provide an additional 580 NSF if Level VL Laboratory is authorized and an additional 150 NSF if a Mass Spectrometer is authorized.

In this area technical personnel employ special and unique diagnostic procedures such as chromatography (thin layer, gas, and/or liquid), atomic absorption spectrophotometry, EMIT and/or manual spectrophotometry, fluorometry etc., to perform therapeutic drug monitoring, toxicology, endocrinology, heavy metal, nutrition and metabolism studies. A reference Laboratory will be utilized for Level S facilities.

3. **Radioimmunoassay (RIA) (LBRI1).....250 NSF (23.3 NSM)**
Minimum NSF if Level L Laboratory is authorized; provide an additional 100 NSF if Level VL Laboratory is authorized.

   In vitro studies utilizing radioisotopes are performed in this area. This laboratory should be carefully planned with adequate radioactive waste disposal facilities with safety hoods to meet standards for inspecting agencies. If hepatitis testing is performed in the laboratory, employee safety must be considered in the design and location of the laboratory. Space for this function will be provided only if there is no Nuclear Medicine Service or radioimmunoassay studies are being performed in Laboratory Service at the time of planning for new construction or renovation. A reference Laboratory will be utilized for Level S facilities.

4. **Urine (Urinalysis) and Feces (LMU03).....50 NSF (4.7 NSM)**
Minimum NSF if Level S Laboratory is authorized; provide an additional 50 NSF if Level M Laboratory is authorized; provide an additional 150 NSF if Level L or Level VL Laboratory are authorized.

   The primary function performed in this area is the biochemical analysis and microscopic examination of urine. Testing feces for normal and abnormal constituents is also performed.

5. **Hematology, Routine Laboratory (LMHI3).....200 NSF (18.6 NSM)**
Minimum NSF if Level S Laboratory is authorized; provide an additional 400 NSF if Level M Laboratory is authorized; provide an additional 900 NSF if Level L Laboratory is authorized and an additional 150 NSF if Cytogenetics is authorized; provide an additional 1,400 NSF if Level VL Laboratory is authorized and an additional 150 NSF if Cytogenetics is authorized.

   The space provided for Levels M, L and VL laboratories includes an 80 NSF administrative work area for a supervisory medical technologist. Levels L and VL include space for electrophoresis and diagnostic cellular immunopathology studies (flow cytometry).

6. **Hematology, Coagulation Laboratory (LMHI3) .....100 NSF (9.3 NSM)**
Minimum NSF if Level S or Level M Laboratory are authorized; provide an additional 50 NSF if Level L or Level VL Laboratory are authorized.

7. **Blood Bank, Blood Product Storage, Testing and Issuance (Transfusion Service) (LMBB2) .....150 NSF (13.9 NSM)**
   Minimum NSF if Level S Laboratory is authorized; provide an additional 100 NSF if Level M Laboratory is authorized; provide an additional 350 NSF if Level L Laboratory is authorized; provide an additional 550 NSF if Level VL Laboratory is authorized.

   The space provided for Levels L and VL laboratories includes an 80 NSF administrative work area for supervisory medical technologists. The term transfusion service usually refers to a facility located in a hospital, organized principally to store, cross match and issue blood for transfusion to patients. An important distinction between a transfusion service and a blood bank is that a transfusion service draws little or no blood. The transfusion service may be the only blood bank function required in the laboratory, if a contractual or sharing agreement exists to provide blood product collection, preparation and/or hemotherapeutics. This area should have walls to provide a quiet work area.

8. **Blood Bank, Blood Product Preparation / Modification (LMBB3).....120 NSF (11.2 NSM)**
   Minimum NSF if Level M Laboratory is authorized; provide an additional 60 NSF if Level L Laboratory is authorized; provide an additional 80 NSF if Level VL Laboratory is authorized.

   This functional area includes the following services, which are required if there is no contract or sharing agreement to provide blood product preparation for the medical center: red cell packing, red cell washing, freezing/rejuvenating, thawing and deglycerolizing, freezing of frozen fresh plasma, thawing of fresh frozen plasma, preparation of cryoprecipitate, thawing of cryoprecipitate, pooling of cryoprecipitate, platelet and granulocyte concentrates from single units, and pooling platelets.

9. **Blood Bank, Hemotherapeutics Room (LMBB1).....200 NSF (18.6 NSM)**
   Provide one if Level M, Level L, or Level VL Laboratory is authorized and if a Hemotherapeutics Blood Bank Room is authorized in Concept of Operations.

   The following functions are performed in this room: the collection of special blood components (white blood cells, platelets etc.) from patients; and the therapeutic removal of plasma (plasmapheresis) or blood cells (cytopheresis).

10. **Blood Bank, Donor Room (LMBB2) .....600 NSF (55.7 NSM)**
    Provide one if Level L or Level VL Laboratory is authorized and if a Blood Bank Donor Room is authorized in Concept of Operations.

    The following primary function is performed in this room: the routine collection of whole blood from donors. This function is required only in large medical centers which have their own established programs for blood donation. There may or may not be a contract or sharing agreement with local agencies to provide some or all of their blood product needs. The space provided includes an enclosed area for the collection of donor history, pre-donation physical examination (blood pressure, etc.) and post-donation recovery

11. **Microbiology, Clinical Microbiology (LMM02) ..... 200 NSF (18.6 NSM)**
Minimum NSF if Level S Laboratory is authorized; provide an additional 400 NSF if Level M Laboratory is authorized; provide an additional 1,400 NSF if Level L Laboratory is authorized; provide an additional 1,900 NSF if Level VL Laboratory is authorized.

    The space provided for levels L and VL laboratories includes a 80 NSF administrative work area for a supervisory medical technologist and a 100 NSF office for clinical laboratory scientists. The space provided was designed to accommodate automated microbiology systems as well as traditional manual microbiology techniques.

12. **Microbiology, Biosafety Laboratory (LMM03)..... 150 NSF (14.0 NSM)**
Minimum NSF if Level S or Level M Laboratory is authorized; provide an additional 100 NSF if Level L Laboratory is authorized; provide an additional 250 NSF if Level VL Laboratory is authorized.

    This area provides isolation facilities for the handling of biologically hazardous specimens and should be environmental separated (negative pressure) for the main laboratory.

13. **Microbiology, Mycology Laboratory (LMM03) ..... 150 NSF (13.9 NSM)**
Provide one if Level L Laboratory or Level VL Laboratory is authorized and if a Microbiology Mycology Laboratory is authorized in Concept of Operations.

    This function is usually provided as part of routine microbiology. This area deals exclusively with the identification of fungi, and in some medical centers, susceptibility testing for anti-fungal drugs.

14. **Microbiology,**
Mycobacteriology (TB) Laboratory (LMM03) ..... 150 NSF (13.9 NSM)
Provide one if Level L Laboratory or Level VL Laboratory is authorized and if a Microbiology Mycobacteriology Laboratory is authorized in Concept of Operations.

    Provided only if TB culture and susceptibility testing is performed in the laboratory and should be environmentally separated (negative pressure) from the main laboratory. This area deals exclusively with the study of TB and (TB-like) microorganisms.

15. **Microbiology,**
Media Preparation Room (LMM02) ..... 200 NSF (18.6 NSM)
Provide one if Level VL Laboratory is authorized.

    For S, M, and L Level Laboratories, the sterilization and solution preparation room can be used for media preparation in these laboratories. This function should be provided only if the cost effectiveness of making media is greater than that provided by purchase of commercial media. It should be provided only for highly specialized reference laboratories that may be able to cost-effectively purchase special media for TB, viral and other organisms with special growth characteristics.

16. **Immunopathology (LMHC1) .....400 NSF (37.2 NSM)**
Minimum NSF if Level M Laboratory is authorized; provide an additional 200 NSF if Level L Laboratory is authorized; provide an additional 400 NSF if Level VL Laboratory is authorized.

    The space provided for Levels L and VL laboratories includes an 80 NSF administrative work area for a supervisory medical technologist. This laboratory comprises all of the services and procedures required to produce diagnostic results based on immunologic (antigen-antibody) reactions using tissues, cells, and fluids.

17. **Fluorescent Microscopy Room (XXYYC).....100 NSF (9.3 NSM)**
Minimum NSF if Level M Laboratory is authorized; provide an additional 50 NSF if Level L Laboratory is authorized; provide an additional 100 NSF if Level VL Laboratory is authorized.

    The interpretation of immunologic diagnostic tests requires a special area, darkened, with adequate ventilation and airflow. As the specialty of immunopathology grows, this area may require expansion to allow more seating area for technical staff at microscopes. The room should be large enough to allow small groups of students and resident physicians to utilize the microscopes, if these programs exist at the medical center, or are planned.

18. **Automated Data Processing (XXYYC) .....70 NSF (6.6 NSM)**
Minimum NSF; provide an additional 30 NSF for each increment of 4 Clinical Pathology Technician / Technologist FTE positions authorized between four and twelve; provide an additional 40 NSF for each increment of 10 Clinical Pathology Technician / Technologist FTE positions authorized greater than twelve.

D. Molecular Testing Suite:

This functional area is required when the laboratory performs specialized testing requiring the extraction, hybridization, amplification, or other analysis of nucleic acids to diagnose disease, predict the prognosis of disease, guide therapy, or evaluate the susceptibility to disease before disease is evident. Given the high potential for contamination during the assay process, laboratory space must be designed to minimize the risk of contamination. Barrier containment through the use of physically separate work areas is required. Laboratory space must also be adequate for the installation of biologic safety cabinets, laminar flow hoods, ultra low temperature freezers, and other required equipment. Other engineering requirements such as negative air flow also apply.

1. **Preamplification Room, Reagent Prep (XXYYC) .....300 NSF (37.2 NSM)**
Provide one per Molecular Testing Suite.

2. **Preamplification Room,**
Specimen Processing (XXYYC).....400 NSF (37.2 NSM)
Provide one per Molecular Testing Suite.

3. **Amplification / Instrument Room (XXYYC).....500 NSF (46.5 NSM)**
Provide one per Molecular Testing Suite.

4. **Developing, Printing and Enlarging Dark Room (XXYYC).....120 NSF (11.2 NSM)**
   Provide one per Molecular Testing Suite if molecular methods to be utilized require photographic development.

5. **Automated Data Processing (XXYYC).....70 NSF (6.6 NSM)**
   Minimum NSF; provide an additional 30 NSF for each increment of four Molecular Testing Technician / Technologist FTE positions authorized between four and twelve; provide an additional 40 NSF for each increment of ten Molecular Testing Technician / Technologist FTE positions authorized greater than twelve.

E. Anatomical Pathology Work Areas:

1. **Histology Laboratory (LMHS2) .....150 NSF (13.9 NSM)**
   Minimum NSF if Level S Laboratory is authorized; provide an additional 250 NSF if Level M Laboratory is authorized; provide an additional 450 NSF if Level L Laboratory is authorized; provide an additional 650 NSF if Level VL Laboratory is authorized.

   The space provided for Levels M, L, and VL laboratories includes an 80 NSF administrative work area for a supervisory medical technologist. In this laboratory tissue, specimens are processed through automated tissue processors, embedded in blocks of paraffin or paraffin-like substances, cut into sections, mounted on microscope slides, and stained for examination by pathologists. The laboratory should be an open laboratory with adjoining adequate secretarial facilities and storage area for pathology records and slides. The laboratory must be adequately ventilated to avoid exposure to toxic fumes and must be equipped with adequate hoods for working with toxic and volatile solvents. Specimen grossing and dissections should be preformed in a safety hood. It should also be provided with adequate safety cabinets for storage of volatile chemicals. Special emphasis should be placed on controlling humidity in the histology area. Air conditioning should be adequate but air movement needs to be distributed evenly and at a fairly low velocity.

2. **Frozen and Gross Section Laboratory (XXYYC).....100 NSF (9.3 NSM)**
   Minimum NSF if Level S Laboratory and Surgery Service are authorized; provide an additional 50 NSF if Level M Laboratory and Surgery Service are authorized; provide an additional 100 NSF if Level L Laboratory is authorized; provide an additional 150 NSF if Level VL Laboratory is authorized.

   This laboratory is necessary to provide space for pathologists to examine tissues from the operating room for rapid (frozen section) diagnostic assistance for surgeons. The area is used daily to examine all of the surgical specimens received from the medical center, and must be adjacent to the histology laboratory. It should be adequately ventilated. In Level L and VL facilities with large surgical volumes consideration should be given to locate the Frozen Section Lab in or adjacent the Surgical Suite or provide proper teleconferencing equipment to mitigate this need.

3. **Cytology Laboratory (LMCY3).....150 NSF (13.9 NSM)**
Minimum NSF if Level M Laboratory is authorized; provide an additional 50 NSF if Level L Laboratory is authorized; provide an additional 100 NSF if Level VL Laboratory is authorized.

   In this area gynecological and non-gynecological cytological specimens are processed, mounted on slides, stained and examined microscopically. Adequate ventilation must be provided. This area should have walls to provide a quiet work area.

4. **Slide, Block and Records Files (SRL01).....200 NSF (18.6 NSM)**
Minimum NSF if Level S Laboratory and Surgery Service are authorized; provide an additional 100 NSF if Level M Laboratory is authorized; provide an additional 200 NSF if Level L Laboratory is authorized; provide an additional 400 NSF if Level VL Laboratory is authorized.

   The location should be designed so that it will provide access in such a way that the secretarial staff can adequately control the utilization of slides, records and quickly retrieve previously filed slides and reports for a pathologist reviewing a case. This area should be planned in a way as to insure adequate storage for slides, tissue blocks, autopsy records, indexing facilities, etc., for 25 years of slides and reports. The histology facilities for autopsy slide preparation should be adjacent to the area just described to allow the histology staff to daily file slides, blocks and preserved tissues. It should be adequately ventilated and provided with regulated temperature control.

5. **Automated Data Processing (XXYYC) .....70 NSF (6.6 NSM)**
Minimum NSF; provide an additional 30 NSF for each increment of four Anatomical Pathology Technician / Technologist FTE positions authorized between four and twelve. Provide an additional 40 NSF for each increment of ten Anatomical Pathology Technician / Technologist FTE positions authorized greater than twelve.

F. Electron Microscopy Suite:

1. **Scope Room (LBEM2).....200 NSF (18.6 NSM)**
Provide one per Electron Microscopy Suite.

2. **Dark Room (LBEM3) .....50 NSF (4.7 NSM)**
Provide one per Electron Microscopy Suite.

3. **Preparation Room (XXYYC).....200 NSF (18.6 NSM)**
Provide one per Electron Microscopy Suite.

4. **Cutting Room (XXYYC).....200 NSF (18.6 NSM)**
Provide one per Electron Microscopy Suite.

5. **Developing, Printing and Enlarging Dark Room (LBEM3) .....120 NSF (11.2 NSM)**
Provide one per Electron Microscopy Suite.

6. **Finishing Room (XXYYC) ..... 120 NSF (11.2 NSM)**
   Provide one per Electron Microscopy Suite and if authorized in Concept of Operations.

7. **Automated Data Processing (XXYYC) ..... 70 NSF (6.6 NSM)**
   Minimum NSF; provide an additional 30 NSF for every increment of four Electron Microscopy Technician / Technologist FTE positions authorized between four and twelve; provide an additional 40 NSF for each increment of ten Electron Microscopy Technician / Technologist FTE positions authorized greater than twelve.

G. Autopsy Suite:

1. **Autopsy Room (LBAR1) ..... 400 NSF (37.2 NSM)**
   Minimum NSF if Level S Laboratory is authorized; provide an additional 200 NSF if Level M Laboratory is authorized; provide an additional 400 NSF if Level L Laboratory or Level VL Laboratory is authorized.

   This area provides the space required to perform post mortem examinations. This room is equipped not only for the performance of autopsies but also for the dissection of organs, tissues, photography of gross specimens and selected diagnostic studies, (e.g., cultures, etc.).

2. **Isolation / Teaching Autopsy Room (XXYYC) ..... 360 NSF (33.4 NSM)**
   Provide one if Level L Laboratory or Level VL Laboratory is authorized.

   This room is equipped to safely perform autopsies on highly infectious cases (AIDS, hepatitis, etc.). It also provides a separate area for demonstrating autopsies to clinicians without interference from or interfering with the performance of other autopsies.

3. **Mortuary Refrigerator (Cold Room) (XXYYC) ..... 100 NSF (9.3 NSM)**
   Minimum NSF if the total number of annual deaths projected is between 1 and 150; provide an additional 20 NSF if the total number of annual deaths projected is between 151 and 300; provide an additional 60 NSF if the total number of annual deaths projected is between 301and 500; provide an additional 100 NSF if the total number of annual deaths projected is between 501 and 700; provide an additional 140 NSF if the total number of annual deaths projected is between 701 and 900; or, provide an additional 180 NSF if the total number of annual deaths projected is greater than 900.

   The "walk-in" type of refrigerator serves the multiple functions of organ storage and body preservation in the most convenient way and with best access for cleaning.

4. **Gross Specimen Storage (XXYYC) ..... 100 NSF (9.3 NSM)**
   Minimum NSF if Level S Laboratory is authorized; provide an additional 50 NSF if Level M Laboratory is authorized; provide an additional 100 NSF if Level L Laboratory is authorized; or, provide an additional 200 NSF if Level VL Laboratory is authorized.

5. **Bathroom, Staff (TLTS1).....120 NSF (11.2 NSM)**
   Provide one per Autopsy Suite.

   This space includes a shower, water closet, urinal and lavatory.

6. **Lockers, Staff (LR002) .....6 NSF (0.6 NSM)**
   Provide 6 NSF per Staff Pathologist FTE position authorized.

7. **Housekeeping Aides Closet - HAC (JANC1) .....40 NSF (3.7 NSM)**
   Provide one per Autopsy Suite.

H. Support Areas:

1. **Storage, Sterilization and Preparation Room (CSSS2).....250 NSF (23.2 NSM)**
   Minimum NSF if Level S Laboratory is authorized; provide an additional 250 NSF if Level M Laboratory is authorized; or, provide an additional 350 NSF if Level L Laboratory or Level VL Laboratory is authorized.

   The environmental safety regulations in many states require sterilization (autoclaving) of items which are contaminated with blood or body fluids. Sterilization is now required in many states for all biological wastes in laboratories. This room also serves a dual function for large volume solution preparation, distilled water preparation and for washing large contaminated items. In Levels S, M, and L laboratories, the bench and sink area can be used to prepare special media for microbiology.

2. **Storage, Bulk (SRS01) .....800 NSF (74.3 NSM)**
   Minimum NSF if Level S Laboratory is authorized; provide an additional 200 NSF if Level M Laboratory is authorized; provide an additional 400 NSF if Level L Laboratory is authorized; or, provide an additional 600 NSF if Level VL Laboratory is authorized.

   This space provides storage for plastic, paper and other dry, non-biological supplies and reagents used to perform tests. Advances in laboratory technology have created a change from glass to disposable plastic ware for nearly all laboratory functions. This area provides space to store and lock valuable items which could easily be stolen (microscopes, small analyzers, typewriters, dictating machines, calculators, etc). If adequate bulk storage is available, it assists in cost reduction, since it gives the laboratory the ability to obtain larger discounts on supplies by purchasing and storing larger amounts. The allocation of storage space may be divided into several storage areas, if desired by the medical center laboratory chief.

3. **Storage, Refrigerated (SRR01).....100 NSF (9.3 NSM)**
   Minimum NSF if Level S Laboratory is authorized; provide an additional 20 NSF if Level M Laboratory is authorized; provide an additional 50 NSF if Level L Laboratory is authorized; or, provide an additional 100 NSF if Level VL Laboratory is authorized.

This area is required to provide controlled temperature storage space to allow the laboratory to buy larger quantities of temperature sensitive, dated biological reagents so that greater discounts can be obtained from manufacturers. In very large, active laboratories, more than one room may be required and this space may be divided into two cold rooms if desired.

4. **Storage, Flammable and Toxic Substance (SRGC2).....100 NSF (9.3 NSM)**
Minimum NSF if Level S or Level M Laboratory is authorized; or, provide an additional 50 NSF if Level L or Level VL Laboratory is authorized.

   This area is needed to comply with OSHA, The Joint Commission, and CAP safety regulations for bulk storage of acetone, formalin, xylene, acids, gas cylinders and any toxic substances which are used in the laboratory. The room should comply with all fire safety regulations in its location. It should be located away from patient care and employee work areas, and should be located on an outside wall, constructed with a blow-out panel. A curb at least 6" in height should be constructed around the base of the room, including the doorsill.

5. **Housekeeping Aides Closet - HAC (JANC1).....40 NSF (3.7 NSM)**
Provide one per Pathology and Laboratory Medicine Service.

I. Staff and Administrative Areas:

1. **Office, Chief of Service (OFC02).....150 NSF (13.9 NSM)**
Provide one per Pathology and Laboratory Medicine Service.

   This office provides space for a workstation, a microscope workstation, and a small conference area.

2. **Office, Section Chief (OFA01 / OFA02).....120 NSF (11.2 NSM)**
Provide one per each Pathology and Laboratory Medicine Service Section Chief FTE position authorized; provide OFA01 if standard furniture is authorized; or, OFA02 if systems furniture is authorized.

3. **Office, Staff Pathologist (OFA01 / OFA02).....120 NSF (11.2 NSM)**
Provide one per each Staff Pathologist FTE position authorized; provide OFA01 if standard furniture is authorized; or, OFA02 if systems furniture is authorized.

4. **Office, Secretary / Waiting (SEC01).....120 NSF (11.2 NSM)**
Provide one per Pathology and Laboratory Medicine Service.

   In addition to reception of visitors, this space will accommodate the storage of laboratory service files, records, inspection and quality control manuals, etc. Addition waiting for ambulatory patients is provided in specimen collection area.

5. **Office, Clerical (OFA03).....80 NSF (7.5 NSM)**
Provide one per each Clerical FTE position authorized.

6. **Office, Administrative Assistant (OFA03).....80 NSF (7.5 NSM)**
Provide one per each Administrative Assistant FTE position authorized.

7. **Office, Chief Medical Technologist (OFA01 / OFA02).....120 NSF (11.2 NSM)**
   Provide one per each Chief Medical Technologist FTE position authorized; provide OFA01 if standard furniture is authorized; or, OFA02 if systems furniture is authorized.

   This person is responsible for the technical and operational management of the laboratory by coordinating budget, equipment and supply procurement, quality control and personnel management (interviewing, scheduling, etc.) functions.

8. **Office, Clinical Laboratory Scientist (OFA01 / OFA02).....120 NSF (11.2 NSM)**
   Provide one per each Clinical Laboratory Scientist FTE position authorized; provide OFA01 if standard furniture is authorized; or, OFA02 if systems furniture is authorized.

   These persons, holding a Ph.D. or M.S. in some chemistry or microbiology specialty are responsible for the day-to-day operation of the chemistry and microbiology laboratory sections.

9. **Conference Room (CRA01) .....350 NSF (32.6 NSM)**
   Provide one per Pathology and Laboratory Medicine Service.

   Dedicated space will be provided for Laboratory Service only when similar space provided for an adjacent service is not available to be shared.

J. Staff Lounge, Lockers, and Toilets:

The spaces below provide programming of Lounge, Lockers, and Toilets at department / service / chapter level. Alternatively, sum all departments/services data for Lockers, Lounges and Toilets, and program space in Chapter 410-EMS Lockers, Lounges, Toilets and Showers. Either/or – do not duplicate space. Program locker space only for those FTEs without office or cubicle space.

1. **Lounge, Staff (SL001) .....80 NSF (7.5 NSM)**
   Minimum NSF; provide an additional 15 NSF per each projected FTE on peak shift greater than five; maximum 210 NSF.

   For less than five FTE combine Lounge facilities with adjacent department or sum in chapter 410.

2. **Locker Room, Staff (LR001) ..... 80 NSF (7.5 NSM)**
   Minimum NSF if total number of FTE positions not authorized to have office or cubicle space is between five and thirteen; provide an additional 6 NSF per FTE position if total number of FTE positions not authorized to have office or cubicle space is greater than thirteen.

Provide locker space only for those FTEs without assigned office or cubicle space. For less than five FTE combine Locker Room facilities with adjacent department or sum in chapter 410.

3. **Toilet, Staff (TLTU1).....50 NSF (4.7 NSM)**
Minimum one; provide an additional staff toilet for each increment of five projected FTEs on peak shift greater than thirteen.

K. Residency Program:

1. **Office, Pathology Resident (OFA01 / OFA02) .....120 NSF (11.2 NSM)**
Provide one per Pathology Resident FTE position authorized and if Residency Program is authorized in Concept of Operations; provide OFA01 if standard furniture is authorized; or, OFA02 if systems furniture is authorized.

2. **Office, Education Coordinator (OFA01 / OFA02).....120 NSF (11.2 NSM)**
Provide one per Education Coordinator FTE position authorized and if a Clinical Laboratory Student Training Program is authorized in Concept of Operations; provide OFA01 if standard furniture is authorized; or, OFA02 if systems furniture is authorized.

3. **Classroom / Laboratory (CRA02).....300 NSF (27.9 NSM)**
Provide one if Classroom / Laboratory for the Residency Program is authorized in Concept of Operations.

4. **Cubicle, Student (OFA03).....35 NSF (3.3 NSM)**
Provide one per Student FTE position authorized and if a Clinical Laboratory Student Training Program is authorized in Concept of Operations.

5. **Library (LIBB1)..... 240 NSF (22.3 NSM)**
Provide one if in Library for the Residency Program is authorized in Concept of Operations.

6 SPACE CRITERIA – OUTPATIENT CLINIC LABORATORY

Refer to Chapter 265: OUTPATIENT CLINIC - Functional Area 18: Pathology and Laboratory Medicine.

7 PLANNING AND DESIGN CONSIDERATIONS

A. Laboratories should be designed to meet changing requirements. Changes in laboratory requirements/new technology dictate flexibility or adaptability of design to patterns of laboratory workflow, deletion of certain procedures and addition of others. Adaptability in interior space means that even walls should be movable in areas where expansion is likely to occur, or workload is likely to alter space requirements due to changes in technology.

B. In new construction the laboratory may be arranged in a radial pattern with or without subdivision into the traditional disciplines. Rapid turnaround time equipment (Automated Processing areas in Clinical Pathology work area) should be co-located

to provide Immediate Response testing, with other equipment located toward the periphery. The more distant portions of the laboratory should be closed off after the daily routine is completed, and work should be clustered near the specimen accessioning and Automated Processing areas to provide a more efficient workflow for technical staff during non-routine hours.

C. If the main laboratory is physically located on the same floor as the ambulatory care area, only one Specimen Collection area is necessary, and it should be located within the main laboratory layout to provide efficiency and reduce staffing. If the main laboratory can not be located convenient to the ambulatory care entrance then a Satellite Patient Specimen Collection Area should be provided with a small after hours Specimen Collection area in the main laboratory. If a Satellite Specimen Collection Areas is required it should be located convenient to the ambulatory care areas and patient entrance as possible. If located in the main laboratory the patient specimen collection area should be located to prevent patient from contact with the Core Laboratory work areas.

D. The specimen processing (accessioning) area should be located at or near the entrance to be used by phlebotomists and/or other staff bringing laboratory specimens to the laboratory.

E. Chemistry, Special Chemistry, Hematology, Urinalysis, and Coagulation have highly automated instrumentation processes and manual processes. It is desirable to centralize the automated processing areas of these departments to allow significantly greater efficiency and faster turnaround time than would be achievable if each of these sections were separately located and staffed. This area performs tests as soon as they arrive in the laboratory so there is no need for a separate Immediate Response Laboratory when this configuration is deployed. If a Pneumatic Tube system is approved one station should be located in this area.

F. It is particularly important that the service oriented (diagnostic) Electron Microscopy Suite be located in close proximity to the frozen and gross section laboratory. It must be integrated with the location of the Immunopathology Laboratory in the Clinical Diagnostic Area; and should not be isolated in a research area which is at some distance from the diagnostic anatomic pathology service. The suite should not be located near anything producing vibrations. Similarly, location near high voltage electrical equipment should be avoided. Since electron microscopes generate an excessive amount of heat, adequate air flow and temperature control is essential in the scope room. Adequate ventilation should be provided.

G. Administrative space and storage are considered “clean” areas; laboratory and processing space are considered “dirty.” Since Laboratory coats must be worn in the dirty areas and cannot be worn in the clean areas, it is helpful to develop a clean/dirty interface that employees must walk through to go from one area to the other. This interface should be a room with hooks on the wall to hang Laboratory coats, a storage cabinet for clean Laboratory coats, and a hand washing sink. Administrative, education/training, and clerical staff space should be located at the periphery of the laboratory, separate from testing areas, but still accessible to the staff.

H. Morgue operations are generally housed in a non-public area accessible to service vehicles; the morgue does not need to be located near the laboratory.

I. The employee entrance to the laboratory should be near the staff locker/changing rooms.

J. Refer to H-08-1, Master Construction Specifications, for special considerations in design that must be given to electrical, air-conditioning, ventilation and mechanical aspects of laboratory construction.

K. Gas, air and vacuum are no longer required in Chemistry and Hematology. Gas may still be required in some Microbiology Laboratories. Fixed gas, air vacuum outlets are no longer needed at the work stations and should be eliminated since they are seldom used. Where needed, vacuum and air may be supplied by small portable pumps and gas may be supplied in small pressurized cylinders.

L. Critical Clearances:

1. Provide a minimum of 1525 mm (5') between laboratory work benches.
2. Provide a minimum of 1525 mm (5') between the end of a Laboratory work bench and the nearest piece of equipment.

M. Consideration should be given to the effects of building vibration, as building vibration could interfere with the accuracy of patient testing.

8 FUNCTIONAL RELATIONSHIPS

Relationship of Pathology and Laboratory Medicine Services to services listed below:

TABLE 1: FUNCTIONAL RELATIONSHIP MATRIX

SERVICES	RELATIONSHIP	REASON
Service Elevators	2	B
Warehouse (for Autopsy Suite)	2	A
Ambulatory Care	3	GH
Dialysis Center	3	I
Intensive Care Nursing Units	3	I
MS&N Patient Care Units	3	I
Supply Service	3	B
Surgical Service (for Anatomical Pathology)	3	C,G
Lobby	X	L

Legend:

Relationship

1. Adjacent
2. Close / Same Floor
3. Close / Different Floor Acceptable
4. Limited Traffic

X. Separation Desirable

Reasons:

(Use as many as appropriate)

A. Common use of resources
B. Accessibility of supplies
C. Urgency of contact
D. Noise or vibration
E. Presence of odors or fumes
F. Contamination hazard
G. Sequence of work
H. Patient's convenience
I. Frequent contact
J. Need for security
K. Others (specify)
L. Closeness inappropriate

9 FUNCTIONAL DIAGRAM