Department of Veterans Affairs **Transmittal Sheet**
Washington, DC 20420 **December 3, 2024**

STAFFING

1. **REASON FOR ISSUE:** To revise the Department of Veterans Affairs (VA) qualification standard for Clinical Laboratory Scientist, GS-0644, (formerly titled Medical Technologist) appointed under the authority of 38 U.S.C. § 7401(3), Appointments in Veterans Health Administration and 38 U.S.C. § 7405(a)(1)(B), temporary full-time appointments, part-time appointments, and without-compensation appointments.

2. **SUMMARY OF CONTENTS/MAJOR CHANGES:** This qualification standard revises the Clinical Laboratory Scientist (formerly titled Medical Technologist) occupation under VA's title 38 hybrid excepted service employment system according to the authority established under P.L. 111-163, Caregivers and Veterans Omnibus Health Services Act of 2010. VA Secretary has authority under 38 U.S.C. § 7402 to prescribe qualifications for occupations identified in or established under 38 U.S.C. § 7401(3), Appointments in Veterans Health Administration and 38 U.S.C. § 7405(a)(1)(B), Temporary full-time appointments, part-time appointments, and without-compensation appointments. The revised standard is effective on the date of this publication. This qualification standard is maintained on the Office of the Chief Human Capital Officer website and the Office of the Chief Human Capital Officer (OCHCO) (va.gov). Significant changes include:

   a. Retitles the existing occupation series from "Medical Technologist" to "Clinical Laboratory Scientist" per the Office of Personnel Management release of the new Job Family Standard for Professional Work in the Medical and Healthcare Group, 0644 series, September 2017.

   b. Revises education and experience requirements.

   c. Changes the full performance level from GS-09 to GS-11.

   d. Removes the GS-10 assignments.

   e. Revises existing assignments and establishes new assignments.

   f. Revises knowledge, skills, and abilities for assignments.

   g. Clarifies assignment titles above the full performance level.

   h. Revises list of applicable certifications.

   i. Creates a route of eligibility for military-trained clinical laboratory professionals.

   j. Allows individuals with categorical and specialty certifications to get appointed and promoted above the full performance level by removing "For grade levels above the full performance level, the candidate must be certified in accordance with paragraph 2d(1) above" from the standard.

k. Extends period for obtaining certification for non-certified individuals from 1 year to 2 years.

3. **RESPONSIBLE OFFICE:** Office of Human Resources and Administration/ Operations, Security, and Preparedness (HRA/OSP) (006), Office of the Chief Human Capital Officer (05), Recruitment and Placement Policy Service (059).

4. **RELATED DIRECTIVES:** . VA Directive 5005, Staffing, April 15, 2002.

5. **RELATED HANDBOOK:** VA Handbook 5005, Staffing, Part II, Appendix G17.

6. **RESCISSIONS:** Medical Technologist Qualification Standard (Former Part II, Appendix G24) dated May 14, 2014.

BY DIRECTION OF THE SECRETARY OF VETERANS AFFAIRS:

/s/
Cassandra M. Law
Assistant Secretary for
Human Resources and Administration/
Operations, Security, and Preparedness

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FORMER VA HANDBOOK REFERENCE: Part II Appendix G24
EFFECTIVE DATE: December 3, 2024

CLINICAL LABORATORY SCIENTIST QUALIFICATION STANDARD GS-0644 VETERANS HEALTH ADMINISTRATION

1. **COVERAGE.** The following are requirements for appointment or placement as a Clinical Laboratory Scientist (CLS) in the Veterans Health Administration (VHA). These requirements apply to all VHA CLS in the General Schedule (GS) 0644 series. In the health care community, a CLS is generally referred to as "Medical Laboratory Scientist" (MLS) or "Medical Technologist" (MT) and these terms are synonymous where stated in this qualification standard. CLS is a certified laboratory professional who performs complex laboratory diagnostic testing on human specimens for diagnosis, treatment, or prevention of disease in clinical laboratory specialties including, but not limited to, Hematology, Chemistry, Immunohematology (Blood Bank), Microbiology, Immunology, Cytogenetics, Anatomic Pathology, Electron Microscopy, Molecular Diagnostics, and Flow Cytometry. A CLS is responsible for performing the pre-analytical, analytical, and post-analytical phases of clinical laboratory testing.

2. **AUTHORITIES.**

   a. P.L. 111-163, Caregivers and Veterans Omnibus Health Services Act of 2010;

   b. 38 U.S.C. § 7401, Appointments in Veterans Health Administration;

   c. 38 U.S.C. § 7402, Qualifications of appointees;

   d. 38 U.S.C. § 7403, Period of appointments; promotions;

   e. 38 U.S.C. § 7405, Temporary full-time appointments, part-time appointments and without-compensation appointments; and

   f. 38 U.S.C. § 7407, Administrative provisions for section 7405 and 7406 appointments.

3. **DEFINITIONS.**

   a. **Appointing Official.** The Human Resources Officer (HRO) is delegated appointing authority to process and authenticate notifications of personnel actions and authority to effect management-approved employment actions on behalf of officials, employees, and facilities for which service is provided.

   b. **Approving Official.** The Veterans Integrated Service Network (VISN) Director, facility Director, or Under Secretary for Health or designee (for VHA Central Office appointments) is the approving official and will determine whether to approve or disapprove the appointment of employees in hybrid occupations.

c. **CLS.** This is the official position title that represents clinical laboratory scientists, medical laboratory scientists, and medical technologists within VA.

d. **Experience.**

(1) **Creditable Experience**. To be creditable, the experience must have required the use of knowledge, skills, and abilities associated with current CLS practices. The experience satisfying this requirement may be paid or non-paid employment as a CLS in the health care field. Research laboratory experience does not fulfill this requirement.

(2) **Part-Time Experience.** Part-time experience is creditable according to its relationship to a full-time workweek. For example, an individual employed 20 hours per week, or on a half-time basis, would receive 1 full-time workweek of credit for each 2 weeks of service.

(3) **Quality of Experience**. Qualifying experience must be at a level comparable to CLS experience at the next lower grade level of the position being filled. For all assignments above the full performance level (FPL), the higher-level duties must consist of significant scope, administrative independence, complexity, and range of variety as described in this standard at the specified grade level and be performed by the incumbent at least 25% of the time.

e. **Journey Level**. The FPL for this qualification standard is the GS-11 grade level.

f. **Medical Laboratory Scientist (MLS).** This title can refer to an organizational position title and/or to the certification credential provided by the American Society for Clinical Pathology Board of Certification (ASCP BOC) or American Medical Technologist (AMT) which is recognized by VA for this occupation series.

g. **Medical Technologist (MT).** This title can refer to an organizational position title and/or to the certification credential provided by AMT and American Society for Clinical Pathology Board of Registry (ASCP BOR), which are both recognized by VA for this occupation series.

h. **Moderate and/or High Complexity Testing**. Clinical laboratory test systems are assigned a moderate or high complexity category based on seven criteria given in the Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations and evaluated by the Food and Drug Administration (FDA). Non-waived testing is the term used to refer collectively to moderate and high complexity testing.

i. **National Accrediting Agency for Clinical Laboratory Science (NAACLS)**. An accreditation agency for ensuring the advancement of education in clinical laboratory sciences and related health care disciplines provided by domestic and international programs.

j. **Occupation.** Refers to positions described in this 0644 CLS series (formerly titled Medical Technologist, GS-0644).

k. **Pathology and Laboratory Medicine Service (P&LMS or PLMS)**. A highly regulated medical service that provides clinical testing on tissues, blood, urine, and other body fluids to aid in the diagnosis and management of disease.

l. **Specialty.** A major section within a clinical laboratory as indicated by CLIA.

m. **VISN.** One of the regional systems of care working together to better meet local health care needs and provide greater access to care.

4. **BASIC REQUIREMENTS.** To qualify for appointment to this position, all applicants must possess the following:

a. **Citizenship.** Be a citizen of the United States (U.S.). Non-citizens may be appointed when it is not possible to recruit qualified citizens in accordance with 38 U.S.C. § 7407(a).

b. **Education**. A bachelor's degree or higher from an accredited college or university. **NOTE:** The Supervisory CLS (Laboratory Director), GS-15, requires unique education requirements. Please reference the education requirements located in that assignment below.

c. **Certification.**

(1) Candidates must meet one of the certification options below.

(a) Generalist certification as an MLS given by ASCP BOC or AMT.

(b) Generalist certification as an MT given by ASCP BOR or AMT.

(c) Categorical certification or Specialist certification by ASCP or AMT.

NOTE: Categorical and specialist certifications are not acceptable for CLS Generalist positions or lab sections unrelated to the categorical or specialist certification held. Categorical or specialist certifications are acceptable for higher-graded positions within the relevant lab section or one of the non-section specific assignments (including, Ancillary Testing Coordinator, Education Coordinator, Laboratory Information Manager, Quality Manager, Laboratory Manager, Regional Technical Specialist, National Quality and Compliance Agent, Regional Program Manager, Regional Director, Laboratory Director, or National Quality and Compliance Officer).

(2) **Exception for Non-Certified.**

(a) Applicants who do not currently hold valid certification may be hired by VA and actively work toward their certification if they meet one of

the routes identified in Appendix A that makes them eligible to take the MLS certification exam through the ASCP BOC or the MLS certification exam through AMT Certification Agency.

(b) Non-Certified applicants who otherwise meet the eligibility requirements for licensure may be given a temporary appointment CLS under the authority of 38 U.S.C. § 7405(c)(2).

(c) Non-Certified individuals may only provide care under the supervision of a certified CLS at or above the FPL.

(d) Non-certified individuals may only be appointed at the entry level and may not be promoted/converted until certification is obtained.

(e) Temporary appointments of non-certified CLS may not be extended beyond 2 years or be converted to a new temporary appointment.

(3) **Failure to Obtain Certification.** In all cases, CLSs must actively work to meet requirements for certification starting from the date of their placement into the occupation. At the time of appointment, the Human Resources (HR) Office staff, in collaboration with the supervisor, will provide the employee with the written requirements for certification, including the time by which the certification must be obtained and the consequences for not becoming certified by the deadline. Failure to obtain certification during this time period may result in separation from employment.

(4) **Loss of Credential.** If an employee fails to maintain the required certification, management officials, in collaboration with HR Office staff, must immediately remove the employee from duties and responsibilities associated with this occupation. This may also result in separation from employment.

(5) If a CLS currently has, or ever had, their CLS certification revoked, suspended, denied, restricted, limited, or issued/placed in a probationary status, HR Office staff must appoint them according to the provisions in VA Handbook 5005, Part II, Chapter 3, Section B, paragraph 16.

d. **Grandfathering Provision.** Employees in VHA in this occupation under a permanent, appropriate, and legal placement on the effective date of this qualification standard, are considered to have met all qualification requirements for the grade and/or assignment held, including positive education and certification where applicable. For employees who do not meet all the basic requirements of this standard but met the qualifications applicable to the position at the time they were appointed, the following provisions apply:

(1) Employees may be reassigned, promoted up to and including the full performance (journey) level, or be changed to a lower grade within the

occupation but may not be promoted beyond the journeyman level or newly placed in supervisory or managerial positions.

(2) If an assignment above the FPL requires an additional certification over and above the basic requirements, employees must meet the assignment-specific requirement before they can be promoted.

(3) Employees who are appointed on a temporary basis prior to the effective date of the qualification standard may not have their temporary appointment extended or be reappointed on a temporary or permanent basis until they fully meet the basic requirements of the standard.

(4) Employees retained in this occupation under this provision who subsequently leave the occupation lose protected status and must meet the full VA qualification standard requirements in effect at the time of re-entry to the occupation.

(5) Employees initially grandfathered into this occupation who subsequently obtain certification that meets all the basic requirements of this qualification standard must maintain the required credentials as a condition of employment in the occupation.

NOTE: This provision is not intended to regularize appointments/ placements.

e. **Foreign Education.** To be creditable, education completed outside the U.S. must be deemed at least equivalent to that gained in a conventional U.S. program by a private organization specializing in the interpretation of foreign educational credentials. Graduates of foreign baccalaureate degree programs meet the educational requirements if they meet either of the following:

(1) Foreign transcripts are evaluated by an acceptable evaluation agency, and the degree is found to be equivalent to a NAACLS-approved U.S. clinical laboratory science degree program.

OR

(2) The applicant submits a letter from ASCP BOC or AMT stating the individual is eligible to take the certification examination.

NOTE: Possession of a certification identified in 4c above automatically determines the foreign education as creditable and no further documentation or proof of equivalency is needed.

f. **Physical Requirements.** See VA Directive and Handbook 5019, Employee Occupational Health Service for requirements.

g. **English Language Proficiency.** Candidates must be proficient in spoken and written English in accordance with 38 U.S.C. § 7403 (f).

5. OFFICIAL POSITION TITLES. All official documents relating to a position (for example, functional statements and personnel actions) must use the approved official title and grade level as described below. For recruitment purposes, HR Offices will use the organizational titles identified in the assignment descriptions below (for example, Supervisory CLS (Laboratory Manager)) in the job opportunity announcement. See VA Handbook 5003, Part I for information on the use of official titles and organizational titles.

a. Clinical Laboratory Scientist, GS-07.

b. Clinical Laboratory Scientist, GS-09.

c. Clinical Laboratory Scientist, GS-11.

d. Clinical Laboratory Scientist (Technical), GS-12.

e. Clinical Laboratory Scientist (Education Coordinator), GS-12.

f. Lead Clinical Laboratory Scientist, GS-12.

g. Supervisory Clinical Laboratory Scientist, GS-12.

h. Clinical Laboratory Scientist (Ancillary Testing Coordinator), GS-12.

i. Clinical Laboratory Scientist (Laboratory Information Manager), GS-12.

j. Clinical Laboratory Scientist (Quality Manager), GS-12.

k. Supervisory Clinical Laboratory Scientist, GS-13.

l. Supervisory Clinical Laboratory Scientist (Laboratory), GS-13.

m. Clinical Laboratory Scientist (Technical), GS-13.

n. Supervisory Clinical Laboratory Scientist (Laboratory), GS-14.

o. Supervisory Clinical Laboratory Scientist, GS-14.

p. Clinical Laboratory Scientist (Quality and Compliance), GS-14.

q. Supervisory Clinical Laboratory Scientist, GS-15.

r. Supervisory Clinical Laboratory Scientist (Laboratory), GS-15.

s. Supervisory Clinical Laboratory Scientist (Quality and Compliance), GS-15.

6. **GRADE DETERMINATIONS.** In addition to the basic requirements for employment, candidates must meet the following grade-determining criteria for placement at grade levels specified.

a. **Clinical Laboratory Scientist, GS-07.**

(1) **Experience.** None beyond the basic requirements.

(2) **Assignment.** Employee at this level serves in a CLS entry-level position. It is expected that they receive guidance from more experienced staff members and require daily direct supervision.

b. **Clinical Laboratory Scientist, GS-09.**

(1) **Experience or Education.** Candidates at this level must meet one of the criteria below:

(a) **Experience.** 1 year of creditable experience equivalent to the next lower grade.

OR

(b) **Education**. Master's degree or 2 academic years of progressively higher-level graduate education in medical technology or a directly related science.

(2) **Knowledge, Skills, and Abilities**. In addition to the experience or education above, the candidate must demonstrate the following KSAs:

(a) Knowledge of policies and procedures of clinical laboratory testing.

(b) Knowledge of laboratory quality control and quality assurance principles.

(c) Knowledge of laboratory equipment and routine maintenance.

(d) Ability to work as a team member and effectively complete assignments.

(e) Ability to read and interpret written instructions.

(f) Ability to accurately perform pre-analytical, analytical, and post-analytical phases of testing.

(3) **Assignment**. An individual at this grade level serves as a developmental CLS. The CLS is responsible for evaluating, performing, interpreting, and validating the accuracy and validity of test results. The CLS demonstrates a clear progression of clinical knowledge and experience by performing testing procedures on a variety of biological specimens using manual or

automated methods. This includes routine testing, quality control, routine maintenance of instrumentation, and troubleshooting that applies innovative procedures and problem solving. Deviations from regular procedures, unanticipated problems, and unfamiliar situations are referred to more experienced staff for a decision or assistance. Assignments at this level will include developmental duties of increasing scope and diversity as compared to the entry level. It is expected that a CLS at this grade performs more complex work while receiving less frequent supervision than at the entry level.

c. **Clinical Laboratory Scientist, GS-11.**

(1) **Experience or Education** Candidates at this level must meet one of the criteria below:

(a) **Experience**. 1 year of creditable experience equivalent to the next lower grade level.

OR

(b) **Education.** Must have 3 full years of progressively higher-level graduate education or a Ph.D. or equivalent doctoral degree in medical technology or a directly related science.

(2) **Knowledge, Skills, and Abilities**. In addition to the experience or education above, the candidate must demonstrate the following KSAs:

(a) Knowledge of professional clinical laboratory science principles, practices, concepts, and theories that support sound, independent work.

(b) Knowledge of laboratory quality control and quality assurance procedures and principles of performance improvement.

(c) Skill in informatics, laboratory data flow, and laboratory processes.

(d) Ability to maintain, troubleshoot, and repair instrumentation.

(e) Ability to use independent technical judgment to analyze and interpret laboratory results.

(f) Ability to read, interpret, and apply complex written instructions.

(g) Ability to communicate, consult, and interact with other members of the health care team, external relations, customer service, and patient education.

(3) **Assignment.** This is considered FPL for a CLS. A CLS at this level independently carries out the day-to-day operations in the laboratory. The CLS develops, performs, evaluates, interprets, correlates, and validates the accuracy of laboratory procedures and results in line with current laboratory regulatory requirements. The work performed may be in a variety of laboratory specialties such as chemistry, microbiology, immunology, hematology, and immunohematology. Testing procedures are performed on a variety of biological specimens and/or environmental samples using manual or automated methods. In addition to routine testing, the CLS conducts quality control and routine maintenance of instrumentation and troubleshooting. The CLS correlates abnormal lab data with pathological states, determines the validity of test results, and the need for additional tests. Specific targeted laboratory responsibilities or projects may include laboratory safety officer, analyzer specialist, primary operator on new test systems, quality control specialist, supply control, and/or coordinator for the laboratory competency assessment or proficiency/survey program. This assignment may include limited duties in areas such as lab information management and ancillary testing. These tasks require a broad exercise of independent judgment and responsibility, including organizing and setting priorities with minimal technical supervision. The CLS assesses a situation, considers the options, and formulates an appropriate course of action. This assignment includes monitoring quality control systems and measures, collaborating in the diagnosis and treatment of patients, and providing education for laboratory health care professionals and the public in a professional, courteous, and effective manner.

d. **Clinical Laboratory Scientist, GS-12, Assignments.**

(1) **Assignments.** For all GS-12 assignments above the FPL, the higher-level duties must consist of significant scope, complexity (difficulty) and range of variety and be performed by the CLS at least 25% of the time. Candidates at this grade level are in one of the following assignments.

(2) **Experience**. 1 year of creditable experience equivalent to the next lower grade level is required for all GS-12 assignments.

(a) **Clinical Laboratory Scientist (Technical Specialist), GS-12**.

i **Knowledge, Skills, and Abilities**. In addition to the experience above, the candidate must demonstrate the following KSAs:

(A) Knowledge and understanding of concepts, principles, methodology of medical laboratory technology, regulatory and accrediting agency requirements, medico-legal requirements, and pertinent statistics sufficient to perform complex diagnostic tests.

(B) Knowledge of instructional techniques to instruct newly hired clinical laboratory scientists and clinical pathology residents in proper performance of tests and applications of laboratory procedures.

(C) Knowledge of one or more advanced clinical laboratory functions.

(D) Skill to apply new scientific/technical developments to develop procedures for new tests and modify existing procedures and methods to resolve problems relative to complex and difficult situations.

(E) Ability to provide guidance and technical direction to accomplish the work of a clinical laboratory.

(F) Ability to provide guidance and technical direction to accomplish the work of the specific laboratory section.

ii **Assignment**. The CLS serves as a Technical Specialist CLS, providing expert authoritative advice and consultation for more markedly difficult, complex, unique and/or emerging tests that require special knowledge. Examples include, but are not limited to, molecular pathology, gas chromatography/mass spectroscopy, and flow cytometry. The CLS advises all organizational levels on various aspects of specialized testing, including appropriateness that takes into consideration clinical context. The CLS advises on alternate testing to overcome ambiguities in the clinical diagnoses and analyzes emerging trends and technology to adopt appropriate methods and testing. The CLS develops policies, precedents, regulatory, licensing, and accrediting requirements to establish, monitor, and maintain the specialized testing. The CLS assumes responsibility for training and competency assessment of staff and students within the area assigned. The technical specialist often works independently and is given freedom of action under the general guidance of a pathologist or other laboratory practitioner.

(b) **Clinical Laboratory Scientist (Education Coordinator), GS-12.**

i **Knowledge, Skills, and Abilities**. In addition to the experience above, the candidate must demonstrate the following KSAs:

(A) Knowledge of medical technology concepts, principles, and practices sufficient to support an educational program for students and continuing education programs for the staff.

(B) Knowledge of the education program's affiliation agreements and accreditation requirements.

(C) Knowledge of a particular specialty or function such as blood banking or molecular diagnostics, to be recognized as a technical authority for instruction.

(D) Knowledge of training methods to conduct continuing education sessions for staff development. The training sessions may be technical in nature or may focus on teaching techniques so that staff can improve their technical skills.

(E) Skill in using educational design, development, evaluation techniques, and teaching methods.

ii **Assignment**. The CLS provides authoritative representation and interaction with a cooperating consortium, affiliated universities, colleges, resource organizations, and state and/or Federal officials to coordinate program goals, objectives, and policies. The CLS may serve on curriculum or admission committees of affiliated colleges. The CLS acts as the clinical education coordinator responsible for organization of all educational activities and relationships with external clinical laboratory educational programs. The CLS will coordinate and administer clinical training programs for medical technology students, facility staff, and others assigned for medical technology training, including formal in service and continuing education programs. The CLS designs, evaluates, and teaches training programs in the areas they are proficient. The CLS establishes, negotiates, and maintains affiliation agreements and schedules students for appropriate rotations. The CLS prepares affiliate student schedules and arranges lectures with educators/instructors. The CLS maintains student records including attendance, evaluation, progress records, and an accurate file of training records for each student for future employment. The CLS must finalize and forward students' final grades to the college and maintain records of the number of clinical hours performed, and so forth. The CLS may develop teaching materials, activities, and handouts for the course and participates in assessment, planning, implementation, and evaluation activities to improve the instructional quality of the course.

(c) **Lead Clinical Laboratory Scientist, GS-12**.

i **Knowledge, Skills, and Abilities**. In addition to the experience or education above, the candidate must demonstrate the following KSAs:

(A) Knowledge of medical technology applicable to a wide range of duties to solve complex problems involving diverse aspects of clinical laboratory practice.

(B) Skill to maintain, troubleshoot, and repair laboratory instrumentation.

(C) Ability to develop procedures for new tests, and modify existing procedures and methods to resolve problems relative to complex and difficult situations.

(D) Ability to manage and coordinate daily work activities and assignments in a section.

(E) Ability to provide or coordinate staff development and training.

(F) Ability to provide guidance and technical direction to a wide variety of individuals including physicians, nurses, and other clinical staff regarding technical aspects of testing, specimen requirements and results.

ii **Assignment.** For all lead assignments, the individual must spend at least 25% or more of their time performing lead duties over staff one grade level below. The Lead CLS communicates the organization's strategic plan, mission, vision, and values. The Lead CLS identifies, distributes, balances work, coaches, and facilitates with problem solving methods. The Lead CLS prepares reports and maintains records of work status; resolves simple, informal complaints; reports performance, progress, and training needs of the team and on behavioral problems; and provides information on promotions, reassignment, recognition of outstanding performance, and personnel needs. The Lead CLS is responsible for all aspects of operation in their area of specialty, including assignment of work responsibilities, workload management, and completion of assignments for staff at or above the FPL as well as preparation and maintenance of records and reports, analysis of testing methodologies, training, instrumentation, and compliance. The Lead CLS may act as a liaison to the supervisor and other departments/divisions of the medical center for the appropriate laboratory specialty. Duties may include, but are not limited to, orientation and evaluating the competency of assigned staff including identification of continuing education and training needs, coordinating daily activity of the lab section(s), writing or modifying technical procedures, providing technical instruction, ensuring that policies, procedures and regulatory requirements are followed,

advising on course of action to follow when results or samples obtained are unacceptable, and coordinating or performing quality control reviews and method verification activities.

(d) **Supervisory Clinical Laboratory Scientist, GS-12.**

i **Knowledge, Skills, and Abilities.** In addition to the experience or education above, the candidate must demonstrate the following KSAs:

(A) Knowledge of Federal and state laws and regulations and laboratory accrediting agency regulatory requirements sufficient to develop plans and procedures for the laboratory.

(B) Knowledge of laboratory quality management procedures and principles sufficient to establish and monitor a laboratory quality management program and/or the education and training of laboratory staff.

(C) Knowledge of concepts, principles, and methods of clinical laboratory technology and operations.

(D) Skill in applying leadership principles such as interpersonal relations and conflict resolution.

(E) Ability to perform the full range of supervisory duties, which includes responsibility for assignment of work, performance evaluations, selection of staff, recommendation of awards, advancements, and disciplinary actions.

(F) Ability to plan, organize, set short and/or long-term goals, and conduct studies on technical and administrative problems including personnel shortages, organizational structure, and new technology.

(G) Ability to manage fiscal matters, forecast resource and equipment needs, and administer the allocated budget.

ii **Assignment.** This assignment is generally found in less complex facilities based on the Hospital Complexity Level as designated in Office of Productivity, Efficiency, and Staffing (OPES) VHA Facility Complexity Model History. **NOTE**: Reference the GS-13 Supervisory CLS assignment to determine the most appropriate assignment for the laboratory. For all supervisory assignments, the CLS must spend 25% or more of their time providing administrative and technical supervision and perform major duties above those at the FPL that consist of significant scope, complexity, difficulty, and variety. The CLS must supervise at

least one staff member at the GS-11 grade level. The supervisory CLS exercises a full range of supervisory responsibilities in planning, directing, and assessing work of subordinate staff. The supervisory CLS ensures that orientation, training, competency assessment, and continuing education requirements are met. The individual ensures compliance with accrediting agencies and regulatory requirements. The supervisory CLS establishes and monitors the quality of pre-analytical processes as part of the overall laboratory quality management program and initiates corrective actions. This individual develops policies and procedures, manages document control, develops performance standards, position descriptions, and functional statements. The supervisory CLS is responsible for professional and administrative oversight of operations, including fiscal and resource management. The supervisory CLS maintains effective interdepartmental relations with other services to accomplish medical center goals.

(e) **Clinical Laboratory Scientist (Ancillary Testing Coordinator), GS-12.**

i **Knowledge, Skills, and Abilities**. In addition to the experience or education above, the candidate must demonstrate the following KSAs:

(A) Knowledge of medical technology concepts, principles, practices, and methodologies sufficient to perform full oversight and guidance for testing programs outside of the laboratory.

(B) Knowledge of mathematics and statistics as related to quality control, quality assurance, proficiency testing, inspection and accreditation, and continuous quality improvement.

(C) Knowledge of Federal, state, and VHA laws, regulations, reference standards, and certifying or accrediting agency requirements to carry out work in each ancillary testing site.

(D) Knowledge of laboratory information technology systems and interconnectivity.

(E) Skill in applying new scientific/technological developments and theories to laboratory testing.

(F) Ability to evaluate, interpret, and teach others to use quality control procedures and implement corrective actions.

ii **Assignment.** The CLS develops and recommends policies and procedures for procurement and service requirements for ancillary testing (testing outside the physical confines of the main laboratory) as mandated by VHA that include ensuring CLIA licenses are maintained for off-site facilities such as Community Based Outpatient Clinics (CBOC). The CLS consults with leadership of clinical services to identify ancillary testing needs, analyzes emerging trends and technology, and adopts appropriate methods. The CLS serves as a recognized technical expert to provide authoritative advice, training, troubleshooting, quality assessment and ancillary testing program consultation. The CLS develops technical bulletins, procedures, training materials, and other program materials. The CLS ensures accreditation and compliance with all regulatory agencies for patient testing, results reporting, and proficiency testing. They also monitor and report on continuous performance improvement initiatives. This individual evaluates ancillary testing activities to assess ongoing day-to-day compliance with established protocols and guidelines. They identify, define, and resolve issues associated with complex aspects of data and problems associated with unique aspects of the ancillary testing management program. The CLS has knowledge of accrediting agencies and regulatory requirements and performs and evaluates instruments, performs validation studies, recommends policy/protocol changes to correct deficiencies, and improves the program. The CLS develops and implements corrective action when deficiencies are identified and coordinates inventory management, supply acquisition, and contracts.

(f) **Clinical Laboratory Scientist (Laboratory Information Manager), GS-12.**

i **Knowledge, Skills, and Abilities**. In addition to the experience or education above, the candidate must demonstrate the following KSAs:

(A) Knowledge of concepts, principles, and methodology of clinical laboratory technology in relation to laboratory information systems.

(B) Knowledge of laboratory operations and their relationship to the organization.

(C) Knowledge of laboratory computer systems sufficient to implement various laboratory associated packages and sustain operation of the laboratory system.

(D) Knowledge of compliance and regulatory requirements for laboratory functions.

(E) Ability to adapt, implement and integrate the use of software to specific laboratory applications and processes, including the use of office automation software.

(F) Ability to independently plan, organize, set priorities, work as a team member, and effectively complete assignments.

ii **Assignment.** The CLS develops and recommends new policies and procedures regarding installation and use of the laboratory information system (LIS) in conjunction with the overall hospital information system (HIS). This individual provides authoritative advice and consultation on the information system as it applies to the clinical laboratory. The CLS advises all organizational levels on functions and capabilities of the LIS. The individual implements and maintains coding and mapping for laboratory test ordering, reporting, billing, and workload recording while considering compliance principles. The CLS analyzes emerging trends, software, and technology and adopts appropriate methods for local programs to meet agency goals. The CLS serves as the local expert for national software developers for testing and validating software packages. They are responsible for compliance with regulatory agency requirements as related to information systems, and they perform audits as needed. The CLS consults with and trains personnel on computer functions, including ordering options, and is responsible for the maintenance of computer security keys.

(g) **Clinical Laboratory Scientist (Quality Manager), GS-12.**

i **Knowledge, Skills, and Abilities.** In addition to the experience or education above, the candidate must demonstrate the following KSAs:

(A) Knowledge of the concepts, principles, and practices of medical technology sufficient to perform the full range of duties involved in planning, coordinating, and evaluating laboratory services.

(B) Knowledge of accrediting agencies and regulatory requirements pertaining to laboratory operations.

(C) Knowledge of laboratory operations and relationships to the organization.

(D) Skill in applying laboratory quality control/assurance policies, procedures, and principles and safety practices and regulations.

(E) Ability to apply quality management performance improvement principles, methodology, and processes to develop and manage a clinical laboratory quality management program.

(F) Ability to apply statistical evaluation and analysis to quality assurance data and implement corrective actions when indicated.

ii **Assignment.** The CLS serves as a consultant, facilitator, trainer, and technical advisor to staff at all levels to ensure facility compliance with clinical laboratory accreditation and regulatory standards that include, but are not limited to, Joint Commission (JC), College of American Pathologists (CAP), and the Office of the Inspector General (OIG). The CLS ensures the laboratory maintains continuous readiness and supports the organization's performance improvement and patient safety programs. The CLS maintains a laboratory performance improvement program, ensures monitoring of components and customer feedback, and interacts with management officials and organizations involved in inter-laboratory quality assurance and proficiency testing. This individual develops, implements, and performs quality management policy review. The CLS advises lab management on quality management concerns that could impact other services and assists with the necessary follow ups. The CLS identifies current lab functions needing improvement and develops a plan with associated individuals to implement change and monitor improvement. The CLS uses comprehensive knowledge for statistical evaluation and analysis and understands laboratory operations and the laboratory's relationship to the organization. The CLS follows laboratory quality control/assurance practices based on policies, procedures, and principles. The individual evaluates and implements new techniques and procedures to address laboratory quality including development of validation plans in terms of equipment, method comparison, and establishment of reference intervals using statistical methods and theoretical knowledge. The CLS provides oversight, guidance, and advice to develop required quality assurance monitors and focused reviews. This individual provides consultative services for laboratory-related root cause analysis, health care failure mode effect analysis, and sentinel events and develops action plans and outcome measures. The CLS establishes processes to

monitor compliance with policies, identify patterns and/or trends, and ensure findings from quality management activities and performance improvement initiatives are used to redesign systems to improve quality. The CLS implements surveillance procedures to monitor variables that affect quality of services. The CLS is skilled in evaluating, interpreting, and teaching others to use quality control procedures and implement corrective actions.

e. **Clinical Laboratory Scientist, GS-13 Assignments.**

(1) **General.** For all GS-13 assignments above the FPL, the higher-level duties must consist of significant scope, complexity (difficulty) and range of variety, and be performed by the CLS at least 25% of the time. Candidates at this grade level are in one of the following assignments.

(2) **Experience.** 1 year of creditable experience equivalent to the next lower grade level is required for all GS-13 assignments.

(a) **Supervisory Clinical Laboratory Scientist, GS-13**.

i The CLS has full supervisory responsibility in a laboratory where at least three of the five following conditions are met outlined below in (A) – (E).

(A) Lab is a complexity level index group 1 or 2 based on the Hospital Complexity Level as designated in Office of Productivity, Efficiency, and Staffing (OPES) VHA Facility Complexity Model History.

(B) The laboratory performs at least one million standard billable tests annually (as reported to the Laboratory Management Index Program).

(C) The CLS supervises a staff of non-supervisory personnel including at least one GS-12 subordinate.

(D) Lack of on-site pathologist.

(E) Oversight of more than one laboratory specialty.

ii **Knowledge, Skills, and Abilities**. In addition to the experience above, the candidate must demonstrate the following KSAs:

(A) Knowledge of Federal and state laws and regulations, laboratory accrediting, and regulatory requirements to develop new policies and guidelines, formulate plans, and judge effectiveness of the operation.

(B) Knowledge of laboratory quality management procedures and principles sufficient to establish and monitor a laboratory quality management program and/or the education and training of laboratory staff.

(C) Skill in interpersonal relations and conflict resolution.

(D) Ability to provide the full range of supervisory duties, which includes responsibility for assignment of work to be performed, performance evaluations, selection of staff, recommendation of awards, advancements, and disciplinary actions.

(E) Ability to analyze organizational, technical, and administrative problems to develop and implement solutions that result in efficient laboratory operation.

(F) Ability to manage fiscal matters, forecast resource and equipment needs, and administer the allocated budget.

(G) Ability to set short and/or long-term goals for the section and conduct studies on technical and administrative problems including personnel shortages, organizational structure, and new technology.

iii **Assignment.** For all supervisory assignments, the CLS must spend 25% or more of their time providing administrative and technical supervision and perform major duties above those at the FPL that consist of significant scope, complexity, difficulty, and variety. The CLS must supervise at least one staff member at the GS-12 grade level. The supervisory CLS exercises a full range of supervisory responsibilities in planning, directing, and assessing work of subordinate staff. The supervisory CLS recommends appointments, awards, advancement, and disciplinary actions. The CLS plans and assigns work based on priorities, requirements of assignments, and abilities of employees; provides advice and counsel; and evaluates work of subordinates. The supervisor ensures compliance with accrediting agencies and regulatory requirements and establishes and monitors the quality of pre-analytical, analytical, and post-analytical processes, initiating corrective actions as needed as part of the overall laboratory quality management program. The supervisory CLS plans and executes performance and quality improvement projects. The supervisory CLS verifies orientation, training, and competency assessment of assigned staff and develops and updates technical policies and procedure manuals. The supervisory CLS ensures all staff and affiliate staff

comply with accrediting and regulating bodies. The supervisory CLS adjusts staffing levels or work procedures to accommodate resource allocation decisions made at the executive level. This individual manages document control, develops performance standards, position descriptions, and functional statements and is responsible for technical and administrative management of an assigned area including budget execution. The supervisory CLS interacts with administrative and clinical onsite personnel and exercises significant independent decision-making authority. The supervisory CLS maintains effective interdisciplinary and interprofessional relations with other services to accomplish medical center goals.

(b) **Supervisory Clinical Laboratory Scientist (Laboratory Manager), GS-13.**

i **Knowledge, Skills, and Abilities**. In addition to the experience or education above, the candidate must demonstrate the following KSAs:

(A) Knowledge of regulatory, licensing, accrediting agency requirements and statutes governing clinical laboratory operations used in planning, implementing, and monitoring laboratory programs and services.

(B) Skill in problem solving and applying analytical and evaluative methods and techniques to measure and improve program effectiveness and/or organizational productivity.

(C) Skill to develop new or modified work methods, organizational structures, records and files, management processes, and staffing patterns.

(D) Skill in administrative management such as budgeting, contracting, procurement, and property management in accordance with VHA regulations.

(E) Ability to balance administrative and clinical functions to coordinate and manage programs and resources.

(F) Ability to plan and execute short-range and long-range programs and/or goals through project management and tactical/strategic planning.

(G) Ability to effectively communicate, orally and in writing, technical information with a wide variety of individuals including senior managers in a medical center or health care

setting or higher-level managers in regional or national offices (for example, VISN-level staff and VHA Central Office staff).

ii **Assignment.** The supervisor serves as a Laboratory Manager (Lab Manager). This assignment is generally found in less complex facilities based on the Hospital Complexity Level as designated in Office of Productivity, Efficiency, and Staffing (OPES) VHA Facility Complexity Model History. **NOTE**: Reference the GS-14 CLS Laboratory Manager assignment to determine the most appropriate assignment for the laboratory. For all supervisory assignments the CLS must spend 25% or more of their time providing administrative and technical supervision and perform major duties above those at the FPL that consist of significant scope, complexity, difficulty, and variety. The CLS must supervise at least one staff member at the GS-12 grade level. The CLS exercises a full range of supervisory responsibilities in planning, directing, and assessing work of subordinate staff. The CLS plans and assigns work based on priorities, requirements of assignments, and abilities of employees; provides advice and counsel; and evaluates work of subordinates. The CLS provides guidance and serves as an authority and subject matter expert on laboratory medicine including research, agency policies, new techniques, and procedures. The CLS develops guidelines, assesses laboratory effectiveness, and establishes and maintains quality assurance and performance improvement programs. The CLS consults with local and network officials. The CLS develops and manages program budget and resource usage, inventory, acquisition, and contracting processes. The CLS assists and participates in educational programs affiliated with institutions that provide training for individuals in laboratory or other related medical fields of study.

(c) **Clinical Laboratory Scientist (Regional Technical Specialist), GS-13.**

i **Knowledge, Skills, and Abilities**. In addition to the experience or education above, the candidate must demonstrate the following KSAs:

(A) Knowledge of regulatory and accrediting agency requirements, concepts, principles, and practices of medical technology sufficient to perform the full range of duties involved in planning, coordinating, and evaluating laboratory services.

(B) Knowledge of compliance requirements sufficient to provide direction for complex diagnostic testing.

(C) Knowledge of laboratory information systems to accomplish diagnostic laboratory work and quality assurance.

(D) Skill in evaluating, interpreting, and teaching others to use quality control procedures to monitor variables that affect quality of services and implement corrective actions.

(E) Ability to apply laws, policies, precedents, regulatory, licensing, and accrediting requirements to establish, monitor, and maintain the specialized testing.

(F) Ability to develop new test procedures and modify existing procedures and methods to resolve problems relative to complex and difficult situations.

ii **Assignment.** The CLS serves as a recognized expert and provides consultative services to management at all levels of the organization advising on various aspects of specialized testing, coordinating VISN or multi-facility specialized services including, but not limited to, quality management or laboratory information management (this list is not all-inclusive). The CLS develops new policies and procedures, conducts studies, recommends changes to correct deficiencies and improve the specialty area, and creates and applies re-engineering and continuous performance improvement initiatives. The CLS analyzes emerging trends, technology, and adopts appropriate methods. The CLS identifies, defines, and resolves issues associated with complex aspects of data or unique/controversial aspects of testing where no direct precedent exists.

f. **Clinical Laboratory Scientist, GS-14. Assignments.**

(1) **General.** For all GS-14 assignments above the FPL, the higher-level duties must consist of significant scope, complexity (difficulty) and range of variety and be performed by the CLS at least 25% of the time. Candidates at this grade level are in one of the following assignments.

(2) **Experience.** 1 year of creditable experience equivalent to the next lower grade level is required for all GS-14 assignments.

(a) **Supervisory Clinical Laboratory Scientist (Laboratory Manager), GS-14.**

i The supervisory CLS serves as the Laboratory Manager (Lab Manager) and shares with the chief of laboratory service/medical

director full responsibility for managing and supervising all phases of laboratory service operations where at least three of the five following criteria are met outlined below in (A) – (E):

(A) The Laboratory is a complexity level index group 1 or group 2 based on the Hospital Complexity Level as designated in Office of Productivity, Efficiency, and Staffing (OPES) VHA Facility Complexity Model History.

(B) The Laboratory performs at least one million standard billable tests annually (as reported to the Laboratory Management Index Program).

(C) The CLS supervises a staff of non-supervisory and supervisory personnel including at least one GS-13 subordinate.

(D) Lack of on-site pathologist/Chief with oversight of a large staff (typically >20 employees).

(E) The CLS oversees additional services (for example, Radiology, Sterile Processing, other).

ii **Knowledge, Skills, and Abilities.** In addition to the experience above, the candidate must demonstrate the following KSAs:

(A) Knowledge of concepts, principles, and methodologies of a major clinical laboratory program and operations to assess program effectiveness and provide authoritative guidance for operations, personnel, and management.

(B) Skill in administrative management such as budgeting, contracting, procurement, and property management in accordance with organizational (for example, VHA) regulations.

(C) Ability to collaborate with other departments and upper management in a medical center or health care setting or higher-level managers in regional or national offices such as VISN-level staff and VHA Central Office staff.

(D) Ability to plan and execute short- and long-range programs and/or goals through project management and tactical/ strategic planning.

(E) Ability to provide advisory, planning, and surveillance services to clinicians, laboratory directors, and supervisors on

specific functions, programs, or problems that are particularly difficult, widespread, or persistent.

(F) Ability to solve complex problems involving unique or controversial aspects of medical technology or laboratory management, new or unconventional methods, program changes or conflicts between scientific/technological requirements and regulatory or program requirements.

(G) Ability to provide the full range of supervisory duties including responsibility for assignment of work, performance evaluations, selection of staff, and recommendation of awards, advancements, and disciplinary actions.

iii **Assignment.** The supervisory CLS serves as the Laboratory Manager (Lab Manager). For all supervisory assignments the CLS must spend 25% or more of their time providing administrative and technical supervision and perform major duties above those at the FPL that consist of significant scope, complexity, difficulty, and variety. The CLS must supervise at least one staff member at the GS-13 grade level. The CLS exercises a full range of supervisory responsibilities in planning, directing, and assessing work of subordinate staff. The CLS provides guidance and serves as an authority and subject matter expert on laboratory medicine including research, agency policies, new techniques, and procedures. This individual develops guidelines, assesses laboratory effectiveness, and establishes and maintains quality assurance and quality management programs. The CLS consults with or serves as a consultant for local, network, and national programs and/or officials. The CLS manages regulatory affairs and compliance and develops and manages program budget and resource usage, inventory, acquisition, and contracting processes. They assist and participate in educational programs affiliated with institutions providing training for individuals in laboratory or other related medical fields of study.

(b) **Supervisory Clinical Laboratory Scientist (National/Regional Program Manager), GS-14.**

i **Knowledge, Skills, and Abilities.** In addition to the experience or education above, the candidate must demonstrate the following KSAs:

(A) Knowledge of principles and methodology of medical technology programs and operations sufficient to assess

program effectiveness to provide authoritative guidance for operations, personnel, and management.

(B) Knowledge of laboratory operations and relationships to the organization.

(C) Skill in administrative management such as budgeting, contracting, procurement, and property management.

(D) Ability to delineate and interpret accreditation standards and regulatory requirements to oversee laboratory programs.

(E) Ability to work collaboratively with other departments and upper management in a medical center or health care setting or higher-level managers in regional or national offices (for example, VISN-level staff and VHA Central Office staff).

(F) Ability to plan and execute short- and long-range programs.

(G) Ability to provide advisory, planning, and surveillance services to clinicians, laboratory directors, and supervisors on specific functions, programs or problems that are particularly difficult, widespread, or persistent.

(H) Ability to solve complex problems involving unique or controversial aspects of laboratory management.

ii **Assignment.** The supervisory CLS serves as a National Program Manager over a Nationwide program (for example Laboratory Information Manager, Telepathology, or Molecular) for P&LMS at the national level or as a Regional Program Manager who manages and oversees multiple laboratories in a region/VISN. For all supervisory assignments, the CLS must spend 25% or more of their time providing administrative and technical supervision and perform major duties above those at the FPL that consist of significant scope, complexity, difficulty, and variety. The CLS must supervise at least one staff member at the GS-13 grade level. The CLS exercises a full range of supervisory responsibilities in planning, directing, and assessing work of subordinate staff. The CLS acts as a liaison and subject matter expert to other sites of the VISN and medical center for the appropriate laboratory areas. The CLS coordinates VISN P&LMS performance measures and data collection; sets laboratory standardized information management policies and VISN or national level performance improvement activities, initiatives, and projects; and oversees instrumentation acquisitions, and other National or VISN contracts. The CLS coordinates discussion between VISN laboratories to ensure

quality compliance with rules and regulations of regulatory agencies such as CAP, JC, American Association of Blood Banks (AABB), and Occupational Safety and Health Administration (OSHA) when dealing with new and evolving technology and regulations. The CLS research methods, performs statistical analyses, monitors quality assurance, prepares and presents reports, and maintains administrative information.

(c) **Clinical Laboratory Scientist, (National Quality and Compliance Agent), GS-14.**

i **Knowledge, Skills, and Abilities.** In addition to the experience or education above, the candidate must demonstrate the following KSAs:

(A) Knowledge of accrediting and regulatory agency requirements.

(B) Skill in application of concepts, principles, and methodology of medical technology sufficient to assess and monitor quality control, quality assurance and proficiency testing in all areas of the laboratory.

(C) Skill with managing laboratory operations and relationships to the organization.

(D) Ability to delineate and interpret accreditation standards.

(E) Ability to perform quality audits and/or inspections of laboratories.

(F) Ability to organize and present the inspection and accreditation rules, regulations, and standards of all laboratory accrediting agencies.

ii **Assignment.** The CLS serves as the National Quality and Compliance Agent and reports to the VHA P&LMS National Enforcement Office in P&LMS at the national level. The CLS serves as an authority to VHA laboratories and conducts quality audits to ensure compliance with accreditation requirements and VHA regulations. The position requires verbal, written, and electronic communication with VISN leadership, VHA hospital directors, VHA laboratories, accrediting organizations, and regulatory bodies such as AABB, CAP, Centers for Medicare & Medicaid Services (CMS), FDA, and JC. The CLS may be appointed to external regulatory accreditation standards boards. The CLS investigates internal and external complaints and

adverse events through resolution. The CLS identifies and facilitates actions related to immediate jeopardy and CLIA sanctions to include suspension, limitation, or revocation and monitors through resolution. The individual participates in national level projects, committees, and boards impacting VHA laboratories Nationwide. The CLS provides authoritative direction and guidance to resolve technical problems and interpretation of existing regulations. The employee develops and maintains procedures related to the enforcement of laboratory regulations and protocols. The CLS ensures VHA laboratories are adequately enrolled with a proficiency provider approved by Department of Health and Human Services (HHS). The CLS conducts external proficiency testing result reviews and evaluation of corrective action for VHA laboratories to ensure quality test results. The individual reviews the accuracy of the CLIA license applications for VHA laboratories, serves as a consultant to national program officials and provides professional, technical, and training support. This assignment was established in accordance with P.L. 102-139 § 101(a).

g. **Clinical Laboratory Scientist, GS-15 Assignments.**

(1) **General.** For all GS-15 assignments at this level, the supervisory duties must consist of significant scope, complexity (difficulty) and range of variety and be performed by the CLS at least 25% of the time. Candidates at this grade level are in one of the following assignments.

(2) **Experience.** 1 year of creditable experience equivalent to the next lower grade level is required for all GS-15 assignments.

(a) **Supervisory Clinical Laboratory Scientist (Regional Director), GS-15.**

i **Knowledge, Skills, and Abilities**. In addition to the experience or education above, the candidate must demonstrate the following KSAs:

(A) Knowledge (technical and operational) related to the clinical laboratory and health care systems.

(B) Skill in solving complex problems involving unique or controversial aspects of medical technology.

(C) Ability to effectively analyze workload, usage, cost efficiency, budget, staffing and quality assurance data and implement corrective actions when indicated.

(D) Ability to develop, implement, monitor, and assess strategic plans and goals to meet mission and program objectives.

(E) Ability to lead people to accomplish objectives.

ii **Assignment.** The supervisory CLS serves as a Regional Director. For all supervisory assignments the CLS must spend 25% or more of their time providing administrative and technical supervision and perform major duties above those at the FPL that consist of significant scope, complexity, difficulty, and variety. The CLS must supervise at least one staff member at the GS-14 grade level. The CLS exercises a full range of supervisory responsibilities in planning, directing, and assessing work of subordinate staff. The CLS serves as a VISN-level director for P&LMS, provides overall technical and administrative direction to the Clinical and Pathology Laboratories, and acts as a liaison to facilities within a VISN. The CLS plans, directs, and coordinates all phases of laboratory service operations in at least three complexity index group level 1 or level 2 laboratories that collectively performs at least three million standard billable tests annually (as reported to the Laboratory Management Index Program). The CLS collaborates with other agencies, VA Central Office (VACO) Program Officials and staff, intra- and inter-VISN and facility leadership and staff, and non-governmental entities to facilitate the implementation of proposed policies and initiatives. The individual negotiates and coordinates the development, acceptance, and application of new standards and guidelines. The CLS secures legal opinions and prepares position papers as applicable. The CLS creates short-term and long-term goals and workplans, including forecasting material and budgetary needs. The CLS has oversight and accountability for multimillion-dollar expenditures. The CLS procures staffing, equipment, reagents, supplies, referral laboratory services, transportation, and other contracted services as needed. The CLS develops processes to improve overall quality, efficiency, and effectiveness of PLMS services and financial management. The CLS also troubleshoots and resolves VISN-wide problems, such as budget shortages, as they arise. The CLS ensures that VISN or system laboratories maintain compliance with regulatory agencies such as CAP, JC, AABB, and Occupational Safety and Health Administration (OSHA).

(b) **Supervisory Clinical Laboratory Scientist (Laboratory Director), GS-15.**

i **Education**. In addition to the 1 year of creditable experience equivalent to the next lower grade level, the candidate must hold

a doctoral degree in clinical laboratory science from an accredited college.

ii **Knowledge, Skills, and Abilities**. In addition to the experience and education above, the candidate must demonstrate the following KSAs:

(A) Knowledge of clinical and anatomic pathology laboratory testing systems and test performance through all phases of testing.

(B) Knowledge of quality assurance requirements to ensure accurate, reliable results that comply with proper regulations and accrediting agency requirements.

(C) Skill in identifying deviations from established performance requirements.

(D) Ability to take remedial action to address performance deficiencies.

(E) Ability to provide leadership and administrative guidance to subordinate staff.

(F) Ability to communicate effectively orally and in writing with a diverse group of professional staff and management officials at all levels.

iii **Assignment.** The supervisory CLS serves as a Laboratory Director. For all supervisory assignments the CLS must spend 25% or more of their time providing administrative and technical supervision and perform major duties above those at the FPL that consist of significant scope, complexity, difficulty, and variety. The CLS must supervise at least one staff member at the GS-14 grade level. The supervisory CLS exercises a full range of supervisory responsibilities in planning, directing, and assessing work of subordinate staff. The CLS is responsible for the overall operation and administration of the laboratory in accordance with 42 C.F.R., part 493. Responsibilities also include ensuring that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which include the pre-analytic, analytic, and post-analytic phases of testing. The CLS ensures the physical plant, LIS, and environmental conditions of the laboratory are appropriate for the testing performed and provide a safe environment where employees are protected from physical, chemical, and biological hazards. The CLS ensures test methodologies selected have the capability of

providing the quality of results required for patient care; verifies procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and that laboratory personnel are performing the test methods, as required, for accurate and reliable results. The CLS also ensures quality control and quality assessment programs are established and maintained to provide quality services and identify failures in quality as they occur. The CLS ensures all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified and that patient test results are reported only when the system is functioning properly. The CLS ensures that consultation is available to the laboratory's clients on matters relating to the quality of test results reported and their interpretation concerning specific patient conditions. The CLS ensures that a supervisor provides on-site supervision of high complexity testing performed by an adequate number of testing personnel qualified under CLIA 42 C.F.R. § 493.1489.

(c) **Supervisory Clinical Laboratory Scientist (National Quality and Compliance Officer), GS-15.**

i **Knowledge, Skills, and Abilities**. In addition to the experience above, the candidate must demonstrate the following KSAs:

(A) Knowledge of laboratory regulation requirements to direct offices on laboratory standard and law.

(B) Knowledge of quality assurance principles to evaluate compliance reports and corrective actions.

(C) Skill in clinical laboratory auditing and/or inspection processes to develop guidance for auditing laboratories.

(D) Skill in communicating in highly unstructured settings with high-ranking officials both inside and outside the organization; this may include VACO-level staff and Congressional stakeholders.

(E) Skill in making convincing oral presentations to senior executives, managers, supervisors, employees, and other diverse audiences.

(F) Ability to evaluate laboratory audit reports and direct actions based on the outcome of those audits.

(G) Ability to successfully manage projects.

ii **Assignment**. The supervisory CLS serves as a National Quality and Compliance Officer for P&LMS at the national level as well as an independent reporting structure to VACO as the internal controls for the enforcement and regulatory authority per the Public Law. For all supervisory assignments, the CLS must spend 25% or more of their time providing administrative and technical supervision and perform major duties above those at the FPL that consist of significant scope, complexity, difficulty, and variety. The CLS must supervise at least one staff member at the GS-14 grade level. The CLS exercises a full range of supervisory responsibilities in planning, directing, and assessing work of subordinate staff. The CLS is responsible for providing and overseeing the administrative functions of the National Enforcement Office (NEO) including budgetary and financial management responsibilities. The CLS oversees regulatory and accreditation operations, VA-wide initiatives and policy implementations pertaining to the laboratory and acts as a liaison to all VHA clinical laboratories. The CLS serves as oversight authority to provide direction to regional offices and supervise National Quality and Compliance Agent CLS subordinates. The CLS ensures the requirements of VHA, national regulatory and accreditation agencies are met. The CLS makes certain national and international VHA clinical laboratories maintain accreditation. In conjunction with the National Quality and Compliance Agents, the CLS provides enforcement of the CLIA regulations for VA laboratories including imposing sanctions and discontinuing laboratory testing. The CLS develops and implements processes to improve overall efficiency, quality, and effectiveness of laboratory services that directly affect the quality of laboratory and related health care services. The CLS establishes and fosters programs necessary to maintain and continuously improve delivery of quality laboratory services across the health care delivery system. The supervisory CLS interfaces with the Centers for Medicare and Medicaid Services (CMS) as the VA representative for the CLIA program. The CLS manages cooperative accreditation and regulatory programs with other organizations including, AABB, CAP, Foundation for the Accreditation of Cellular Therapy (FACT), American Society of Histocompatibility and Immunogenetics (ASHI), JC, CMS, FDA, HHS, Health Resources and Services Administration (HRSA), and various state agencies when dealing with new and evolving technology and regulations. The CLS addresses Congressional inquiries and provides testimonies as needed. This assignment was established in accordance with P.L. 102-139 § 101(a). The NEO ensures compliance with P.L. § 100-578, CLIA of 1988, P.L. 102-139, 38 U.S.C. § 17.3500, VA Application of 42 C.F.R.,

part 493 Standards for Clinical Laboratory Operation and 42 C.F.R., part 493, Laboratory Requirements.

7. DEVIATIONS.

a. The establishment of a position and subsequent placement of an individual in a grade or assignment not described in the hybrid title 38 qualification standard must be approved by the Under Secretary for Health or designee prior to placement.

b. Under no circumstance will educational requirements necessary to meet basic qualifications or assignment-specific educational requirements be waived.

c. Under no circumstance will the credential (for example, license, certification, and/or registration) requirements to meet basic qualifications or assignment-specific credentials be waived unless an exception provision is provided in the qualification standard.

d. In rare and unusual circumstance(s), the Under Secretary for Health or designee may approve requests for reasonable deviations to the grade determination requirements for an individual whose composite record of experience, accomplishments, performance, and qualifications warrant such action based on demonstrated competence to meet the requirements of the grade and/or assignment.

RESPONSIBLE OFFICE: Human Resources and Administration/Operations, Security, and Preparedness (HRA/OSP) (006), Office of the Chief Human Capital Officer (OCHCO) (05), Recruitment and Placement Policy Service (059).

APPENDIX A: ELIGIBLITY ROUTE DECISION TABLE

VA HR Office staff can hire applicants who do not currently hold valid certification, but actively work toward their certification. Applicants must meet one of the eligibility routes to take the MLS certification exam through the ASCP BOC or through AMT Certification Agency. These routes are located on these agencies' websites and are as follows:

ROUTE	EDUCATION	CERTIFICATION	MILITARY TRAINING	EXPERIENCE
#1 Education and Experience must be met	A bachelor's degree or higher from an accredited college or university in medical laboratory science, medical technology, clinical laboratory science, or in a related science (for example, chemistry, biochemistry, biology, microbiology, immunology, etc.)	Not Applicable *Certification must be obtained within 2 years of temporary appointment	Not Applicable	Completion of a medical technology clinical practice program within the last 5 years. Clinical practice programs completed after 1974 must be accredited by the NAACLS, Commission on Accreditation of Allied Health Education Programs (CAAHEP, formerly CAHEA), or the Accrediting Bureau of Health Education Schools (ABHES). The professional curriculum may have consisted of a post-baccalaureate certificate program or be integrated into a 4-year program of study that culminated in a baccalaureate degree.
#2 Education, Certification, and Experience must be met	A bachelor's degree from an accredited college/university including 16 semester hours (24 quarter hours) of biological science (with one course in microbiology), 16 semester hours (24 quarter hours) of chemistry (with one course in organic or biochemistry*), and	Valid Medical Laboratory Technician (MLT) certification by the ASCP BOC, ASCP BOR, or AMT	Not Applicable	1 year of post-MLT certification clinical laboratory experience within the last 3 years. This experience must include performing moderate and/or high complexity testing (as categorized by the FDA) in a clinical laboratory. Research laboratory experience does not fulfill this requirement.

ROUTE	EDUCATION	CERTIFICATION	MILITARY TRAINING	EXPERIENCE
	one course in mathematics			
#3 Education and Experience must be met	A bachelor's degree from an accredited college/university including 16 semester hours (24 quarter hours) of biological science (with one course in microbiology), 16 semester hours (24 quarter hours) of chemistry (with one course in organic or biochemistry*), and one course in mathematics	Not Applicable *Certification must be obtained within 2 years of temporary appointment	Not Applicable	4 years of clinical laboratory experience within the last nine years performing moderate and/or high complexity testing in blood bank, chemistry, hematology, microbiology, immunology, and clinical microscopy (or categorical experience that matches categorical certification) in a clinical laboratory.
#4 Education, Military Training, and Experience must be met	A bachelor's degree from an accredited college/university with 16 semester hours (24 quarter hours) in biology including one semester in microbiology and 16 semester hours (24 quarter hours) in chemistry, which may be obtained within or in addition to, the bachelor's degree	Not Applicable *Certification must be obtained within 2 years of temporary appointment	Completion of a 50-week U.S. Military MLT training program (with official certificate verifying completion of training) within the last 10 years	1 year full-time clinical laboratory experience within the last 10 years. This experience must include performing moderate and/or high complexity testing in blood banking, chemistry, hematology, microbiology, immunology, and urinalysis/body fluids (or categorical experience that matches categorical certification) in a clinical laboratory. Research laboratory experience does not fulfill this requirement.

***NOTE:** The successful completion of a NAACLS accredited MLS (certificate) program, NAACLS, ABHES accredited MLT program, or a foreign medical laboratory science clinical training program within the last 5 years can be used in lieu of completion of 1 semester of organic or biochemistry.