

## STAFFING

- 1. REASON FOR ISSUE:** To establish a Department of Veterans Affairs (VA) qualification standard for Cytotechnologist, General Schedule (GS) 0601, appointed under 38 U.S.C. § 7401(3) and 38 U.S.C. § 7405(a)(1)(B).
- 2. SUMMARY OF CONTENTS/MAJOR CHANGES:** This handbook contains mandatory procedures on staffing. This policy establishes qualification standards for the cytotechnologist occupation. The policy is established under VA's title 38 hybrid excepted service employment system, and the authority of Public Law 111-163, "Caregivers and Veterans Omnibus Health Services Act of 2010." Authority is given to the Secretary of VA under 38 U.S.C. § 7402(b), to prescribe qualifications for occupations identified in or established under 38 U.S.C. § 7401(3) and 38 U.S.C. § 7405(a)(1)(B). These changes will be incorporated into the electronic version of VA Handbook 5005 that is maintained on the Office of Human Resources Management Website.
- 3. RESPONSIBLE OFFICE:** Recruitment and Placement Policy Service (059), Office of the Chief Human Capital Officer.
- 4. RELATED DIRECTIVE:** VA Directive 5005, Staffing.
- 5. RESCISSIONS:** None.

**CERTIFIED BY:**

**BY DIRECTION OF THE SECRETARY OF  
VETERANS AFFAIRS:**

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**DISTRIBUTION:** Electronic Only

**NOTE:** This transmittal page accompanied the former VA Handbook 5005, Staffing publication. It is provided for reference to the establishment of this qualification standard.

**CYTOTECHNOLOGIST  
QUALIFICATION STANDARD  
GS-0601  
Veterans Health Administration**

- 1. COVERAGE.** The following are requirements for appointment as a cytotechnologist in the Veterans Health Administration (VHA). The requirements apply to all VHA cytotechnologists employed in the General Schedule (GS)-0601 series. Cytotechnologists are certified laboratory professionals performing highly complex laboratory diagnostic testing on human specimens for diagnosis, treatment, or prevention of disease in the laboratory specialty of cytopathology. Cytotechnologists are solely responsible for: reporting the microscopic interpretation of normal pap smear tests used to detect cervical cancer; providing preliminary interpretation of specimens from other body sites; and collaborating with pathologists to diagnose benign and infectious processes, precancerous lesions, and malignant diseases.
- 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;](#)
  - f. [38 U.S.C. § 7407, Administrative provisions for section 7405 and 7406 appointments.](#)
- 3. DEFINITIONS.**
  - a. **Journey Level.** The full performance level for this qualification standard is the GS-9 grade level.
  - b. **Creditable Experience.** To be creditable, the experience must have required the use of knowledge, skills, abilities (KSAs), and other characteristics, also referred to as core competencies; be associated with the scope of cytotechnologist practice equivalent to at least the next lower grade level; be directly related to the position being filled; and may be paid or non-paid employment.
  - c. **Part-Time Experience.** Part-time experience is creditable according to its relationship to the full-time work week. For example, a cytotechnologist employed 20 hours per week, or on a half

time basis, would receive one full-time work week of credit for each two weeks of service.

**4. BASIC REQUIREMENTS.** To qualify for appointment as a cytotechnologist, all applicants must possess the following:

- a. **Citizenship.** Citizen of the United States (U.S.). (Non-citizens may be appointed when it is not possible to recruit qualified citizens in accordance with chapter 3, section A, paragraph 3g, of this part.)
- b. **Education.** Individuals must have successfully completed a baccalaureate degree from a regionally accredited college/university and successfully completed a Commission on Accreditation of Allied Health Education Programs accredited cytotechnology program.
- c. **Foreign Education.** To be creditable, education completed outside the U.S. must have been submitted to a private organization approved by the American Society for Clinical Pathology (ASCP) that specializes in the interpretation of foreign educational credentials and such education must have been deemed at least equivalent to that gained in conventional U.S. programs.
- d. **Certification**
  - (1) Candidates must currently possess the Cytotechnologist (CT) (ASCP) or Specialist in Cytotechnology (SCT) (ASCP) certification given by the ASCP Board of Certification.
  - (2) **Loss of Certification.** An employee who fails to maintain the required certification must be removed from the occupation, which may also result in termination of employment.
- e. **Grandfathering Provision.** All cytotechnologists employed in VHA, in this occupational series, performing the duties as described in the qualification standard on the effective date of this qualification standard, are considered to have met all the qualification requirements for the grade held, including positive education and certification that are part of the basic requirements of the occupation. 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 to the position, the following provisions apply:
  - (1) Cytotechnologists that do not meet the basic requirements for education and certification may be reassigned, promoted up to and including the full performance level, or demoted within the occupation, but may not be promoted beyond the full performance level or placed in supervisory or managerial positions.
  - (2) Cytotechnologists 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.
  - (3) Cytotechnologists initially grandfathered into this occupation, who subsequently obtain education and/or certification that meets all the basic requirements of this qualification standard, must maintain the required credentials as a condition of employment in the occupation.

(4) Cytotechnologists who were retained in this occupation, under this provision, and subsequently leave the occupation, lose protected status and must meet the full VA qualification standard requirements in effect at the time of reentry to the occupation.

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

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

**5. GRADE REQUIREMENTS.** All individuals assigned to this occupation must have an approved title or parenthetical title, as described below:

a. Cytotechnologist

b. Lead Cytotechnologist

c. Cytotechnologist (Quality Management)

d. Supervisory Cytotechnologist

e. Cytotechnologist (Laboratory Information Manager)

f. Supervisory Cytotechnologist (Laboratory Manager)

g. Cytotechnologist (Regional Commissioner Technologist)

h. Cytotechnologist (Laboratory Director)

## **6. GRADE DETERMINATIONS**

a. **Grade Determinations.** In addition to the basic requirements for employment, the following criteria must be met when determining the grade of candidates:

### **(1) Cytotechnologist, GS-7**

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

(b) **Assignment.** At the entry level, cytotechnologists serve in a career development position practicing under close supervision of a supervisor, lab manager, or qualified individual who reviews and ensures the employee meets competency requirements.

### **(2) Cytotechnologist, GS-9**

(a) **Experience.** At this level, the candidate must have one year of creditable experience equivalent to the GS-7 grade level that is directly related to the position to be filled.

(b) **Assignment.** At the journey level, the cytotechnologist independently reviews clinical data of patients and evaluates all cytology preparations by light microscopy for the presence or absence of cellular patterns, presence of micro-organisms, inflammatory reactions, endocrinopathies, benign changes, pre-malignant changes,

neoplasia, and cellular responses to therapeutic agents. The cytotechnologist issues and verifies the final diagnosis for negative gynecologic specimens. The cytotechnologist prioritizes, prepares, and processes all specimens for cytodiagnostic and immunohistochemical testing in compliance with the guidelines of regulatory agencies. The cytotechnologist instructs others on the proper collection methods and transportation of specimens and determines acceptability of patient samples for processing. The cytotechnologist performs routine maintenance of equipment using standard operating procedures.

(c) **Demonstrated Knowledge, Skills, and Abilities.** In addition to the experience above, the candidate must demonstrate all of the following KSAs:

- i. Ability to review clinical data of patients, relate data to microscopic findings, and evaluate all cytology preparations by light microscopy for the presence or absence of cellular patterns, presence of micro-organisms, inflammatory reactions, endocrinopathies, benign changes, pre-malignant changes, neoplasia, and cellular responses to therapeutic agents.
- ii. Ability to make a preliminary cytodiagnosis to issue and verify the final diagnosis for gynecologic specimens interpreted to be negative.
- iii. Knowledge of processes and procedures to prepare all specimens for cytodiagnostic and immunochemistry testing, as well as filtration methods, preparation, fixation, and staining of slides.
- iv. Ability to instruct others on the proper collection methods and transportation of specimens, and to determine acceptability of patient samples for processing.
- v. Knowledge of the standards of regulatory agencies, such as those of Joint Commission (JC), College of American Pathologists (CAP), Clinical Laboratory Improvement Amendment (CLIA), and Occupational Safety and Health Administration (OSHA), to ensure compliance with requirements and guidelines.
- vi. Ability to perform routine maintenance of laboratory equipment according to standard operating procedures.
- vii. Skill in prioritizing workflow/specimen triage.

### (3) Cytotechnologist, GS-11

- (a) **Experience.** The candidate must have one year of creditable experience equivalent to the journey level (GS-9) that is directly related to the position to be filled.
- (b) **Assignments.** For all assignments above the journey level, the higher-level duties must consist of significant scope, complexity (difficulty), range of variety, and be performed by the incumbent at least 25% of the time. At the advanced level, the cytotechnologist independently performs and monitors processes such as smear preparation, slide fixation, cell block preparation, monolayer filtration processing, and staining. If a discrepancy is identified with these processes, the cytotechnologist will troubleshoot and take corrective action. The cytotechnologist may act as a technical

resource in writing and establishing new processes or procedures. The cytotechnologist performs a full range of specialized tasks, including collecting, compiling, and analyzing data according to the laboratory quality management program. The cytotechnologist uses these laboratory data to implement any needed quality improvement initiatives. The incumbent will research, test, validate, and implement new procedures and equipment.

**NOTE:** Advanced assignments may also include one or more of the tasks identified below. When these duties are required, the Advanced Cytotechnologist must also demonstrate the corresponding advanced KSAs as identified by the corresponding asterisk(s) below in KSA (c) v. - (c) viii. These KSAs are:

\*\*Electron Microscopy (KSA (c) v.): Ability to utilize electron microscope, performance of ultrathin cryomicrotomy, and staining of ultrastructural components.

\*\*\*Safety Coordination (KSA (c) vi.): Ability to oversee safe handling of specimens, chemicals, and equipment by all staff and ensures adherence to safety regulations.

\*\*\*\*Laboratory Education (KSA (c) vii.): Ability to plan and administer an ongoing continuing education program for laboratory staff to meet accreditation requirements.

\*\*\*\*\*Automated Data Processing Applications Coordinator (KSA (c) viii.): Ability to carry out day-to-day operations related to laboratory information systems/computer use and system maintenance.

(c) **Demonstrated Knowledge, Skills, and Abilities.** In addition to the experience above, the candidate must demonstrate the KSAs i. - iv. and the advanced KSA as identified by the corresponding asterisk(s):

i. Ability to independently determine specimen adequacy using complex specialized testing methods or techniques during Endoscopic Ultrasound, Endobronchial Ultrasound, and other Fine Needle Aspiration procedures.

ii. Knowledge of pre-analytical, analytical, and post-analytical processes to establish and monitor the overall laboratory quality management and quality control program, and initiate corrective action as needed.

iii. Skill in collecting, compiling, and analyzing data for quality assurance, statistics, trends and reports, and implementing quality improvement initiatives.

iv. Skill in researching, testing, validating, and implementing new procedures and equipment.

v. \*\*Ability to perform ultrathin microtomy and operate an electron microscope. Knowledge of microanatomy sufficient to note ultrastructural and microchemical findings.

vi. \*\*\*Ability to convey knowledge of safety regulations and guidelines such as CAP, JC, and OSHA, and to ensure staff compliance with safety requirements, including continuing education and employee orientation.

vii. \*\*\*\*Knowledge and skill to plan and administer an ongoing continuing education program for the laboratory to meet accreditation standards.

viii.\*\*\*\*\*Skill to maintain and troubleshoot computers and laboratory system instrumentation.

#### (4) **Lead Cytotechnologist, GS-11**

- (a) **Experience.** The candidate must have one year of creditable experience equivalent to the journey level (GS-9) that is directly related to the position to be filled.
- (b) **Assignments.** For all assignments above the journey level, the higher-level duties must consist of significant scope, complexity (difficulty), range of variety, and be performed by the incumbent at least 25% of the time. The lead cytotechnologist provides direction to cytology staff by overseeing daily operations of the cytology laboratory. The incumbent monitors the processing of cytology preparations, including associated quality control measures. The lead cytotechnologist establishes procedure manuals and forms necessary to meet departmental and regulatory needs. The lead cytotechnologist will research, test, validate, and implement new procedures and equipment. The lead cytotechnologist monitors abnormal test results, notifies the physician when necessary, and completes documentation in accordance with CAP requirements. The lead cytotechnologist will monitor and make work assignments, provide input on performance, resolve daily workplace issues, and maintain efficient workflow. Assignments at this level include, but are not limited to: assuring coverage of all areas of responsibility; conducting ongoing reviews to ensure quality of work; providing guidance to staff members to include changes in policies and procedures; distributing and balancing workload; orienting and providing on-the-job training for new and current employees; ensuring all training requirements are met; and organizing the work structure of the assigned area.
- (c) **Demonstrated Knowledge, Skills, and Abilities.** In addition to the experience above, the candidate must demonstrate all of the following KSAs:
- i. Skill in researching, testing, validating, and implementing new procedures and equipment.
  - ii. Ability to monitor abnormal test results, which includes notification to the physician when necessary, and to complete documentation in accordance with CAP requirements.
  - iii. Ability to lead others, monitor and make work assignments, balance workload, and ensure duties are completed in an accurate and timely manner. This includes the ability to follow-up on pending issues and demonstrate an understanding of the impact of incomplete work.
  - iv. Knowledge of laboratory requirements to develop, maintain, and issue written instructions and standard operating procedures, including the design of forms that comply with regulatory agencies.

#### (5) **Cytotechnologist (Quality Management), GS-11**

- (a) **Experience.** The candidate must have one year of creditable experience equivalent to the journey level (GS-9) that is directly related to the position to be filled.

(b) **Assignments.** For all assignments above the journey level, the higher-level duties must consist of significant scope, complexity (difficulty), range of variety, and be performed by the incumbent at least 25% of the time. In this assignment, the cytotechnologist provides authoritative advice and consultation on quality management laboratory services to all levels of management throughout the organization. The cytotechnologist maintains a laboratory quality management program and ensures monitoring of components and customer feedback. The cytotechnologist analyzes, identifies, defines, and resolves issues associated with complex aspects of the collected data. The cytotechnologist monitors laboratory quality control systems and performance indicators. The cytotechnologist interacts with management officials and vendors, providing inter-laboratory quality assurance and laboratory proficiency testing. The cytotechnologist is responsible for a laboratory's continuous readiness for regulating agency inspections and accreditation from agencies, such as JC and CAP.

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

- i. Comprehensive knowledge of laboratory quality control/assurance policies, quality management standards, procedures and principles, as well as safety practices and regulations.
- ii. Knowledge of accrediting agencies and regulatory requirements pertaining to laboratory operations, and skill in ensuring continuous readiness for inspections.
- iii. Knowledge of laboratory operations and relationships to the organization.
- iv. Ability to analyze quality assurance data and resolve complex data issues.
- v. Knowledge of anatomic pathology, clinical laboratory, and ancillary testing.

#### (6) **Cytotechnologist (Supervisory), GS-12**

(a) **Experience.** At this level, the candidate must have one year of creditable experience equivalent to the GS-11 grade level that is directly related to the position to be filled.

(b) **Assignments.** For all assignments above the journey level, the higher-level duties must consist of significant scope, complexity (difficulty), range of variety, and be performed by the incumbent at least 25% of the time. The supervisory cytotechnologist performs a full range of supervisory duties for one or more sections of the laboratory. The supervisor makes work assignments, writes performance evaluations and staff competencies, and solves administrative problems. The supervisory cytotechnologist plans, organizes, and communicates management goals, and ensures compliance with regulations. The cytotechnologist is able to demonstrate leadership and managerial skills, including interpersonal relations and conflict resolution, to effectively interact with employees, team leads, and managers. The supervisory cytotechnologist uses federal and state laws, regulations, and laboratory quality management procedures and principles to develop plans that aid in the laboratory quality management program and education, testing, and training of staff. In accordance with the CAP guidelines, the cytotechnologist may be



responsible for rescreening previously screened negative cases and those designated "high risk" cases, before the diagnostic interpretation is released from the cytopathology laboratory.

- (c) **Demonstrated Knowledge, Skills, and Abilities.** In addition to the experience above, the candidate must demonstrate all of the following KSAs:
- i. Demonstrated leadership and managerial skills, including interpersonal relations and conflict resolution to effectively interact with employees, team leaders, and managers.
  - ii. 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.
  - iii. Skill in communicating management goals with individuals to obtain the desired effect, while ensuring compliance with established policies and regulations.
  - iv. Ability to perform the full range of supervisory duties, which includes responsibility for assignment of work, performance evaluations, maintenance of staff competencies, selection of staff, recommendation of awards, advancements, and disciplinary actions, as appropriate.
  - v. Knowledge of federal and state laws, regulations, and accrediting/regulatory requirements to develop plans and procedures for the laboratory.
  - vi. Knowledge of laboratory quality management procedures and principles sufficient to establish and monitor a laboratory quality management program and/or education and training of laboratory staff, including annual CLIA proficiency testing.
  - vii. Ability to rescreen previously screened negative cases, including those designated as "high risk" cases, before the diagnostic interpretation is released from the cytopathology laboratory.

## **(7) Cytotechnologist (Laboratory Information Manager), GS-12**

- (a) **Experience.** At this level, the candidate must have one year of creditable experience equivalent to the GS-11 grade level that is directly related to the position to be filled.
- (b) **Assignments.** For all assignments above the journey level, the higher-level duties must consist of significant scope, complexity (difficulty), range of variety, and be performed by the incumbent at least 25% of the time. The laboratory information manager develops and recommends new policies and procedures regarding the installation of evolving tests or techniques, and the use of the laboratory information system (LIS). The laboratory information manager ensures compatibility of the LIS with the overall hospital information system (HIS), and provides authoritative advice and consultation regarding the functions and capabilities of the LIS to all levels of the

organization. The laboratory information manager implements and maintains coding and mapping for laboratory test ordering, reporting, billing and workload recording, while considering compliance principles. The laboratory information manager analyzes emerging trends, software and technology, and adopts appropriate methods for local programs to meet agency goals. The laboratory information manager serves as the local expert representing the lab end users, by interacting with software developers to test and validate new and emerging software packages. The laboratory information manager is responsible for compliance with regulatory agency requirements, as related to information systems, and performs audits, as needed. The laboratory information manager provides consultation and training of personnel on computer functions, including ordering options, and is responsible for the maintenance of computer security keys.

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

- i. Knowledge and understanding of laboratory operations, and compliance and regulatory requirements to provide advice, training, and problem-solving services on specific projects, programs, or functions, in order to conduct inspections and audits, as needed.
- ii. Ability to independently plan, organize, set priorities, work as a team member, and effectively complete assignments.
- iii. Skill in using the laboratory information system, program techniques, computer language, and program design sufficient to implement various laboratory associated packages and sustain operation of the laboratory system.
- iv. Ability to adapt, implement, and integrate the use of software to specific laboratory applications and processes, including the use of office automation software.

#### (8) **Supervisory Cytotechnologist (Laboratory Manager), GS-13**

- (a) **Experience.** At this level, the candidate must have one year of creditable experience equivalent to the next lower grade level that is directly related to the position to be filled.
- (b) **Assignments.** For all assignments above the journey level, the higher-level duties must consist of significant scope, complexity (difficulty), range of variety, and be performed by the incumbent at least 25% of the time. The supervisory cytotechnologist (laboratory manager) reports to the director of the laboratory

service. The incumbent is responsible for supervising a large staff of nonsupervisory and supervisory personnel, and for managing and overseeing laboratory service operations. The incumbent also provides guidance and serves as an authority and subject matter expert on laboratory medicine, including research, agency policies, new techniques and procedures, developing guidelines, assessing laboratory effectiveness, and for establishing and maintaining quality assurance and quality management programs. The laboratory manager consults with, or serves as a consultant for, local, network, and national programs and/or officials; manages regulatory affairs and compliance; and develops and manages program budget and resource utilization, inventory, acquisition, and contracting processes.

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

- i. Knowledge of the requirements of regulatory, licensing, accrediting agency, and laws governing clinical laboratory operations used in planning, implementing, and monitoring laboratory programs.
- ii. Ability to plan and execute short- and long-term programs and/or goals, through project management and tactical/strategic planning.
- iii. Ability to work collaboratively with other disciplines, upper management, and executive leadership.
- iv. Advanced knowledge of concepts, principles, and methodology of operations for a major clinical laboratory program, so as to assess program effectiveness and provide authoritative guidance of operations, personnel, and management.
- v. Skill in administrative management (e.g., budgeting, contracting, procurement, and property management) in accordance with regulations.
- vi. Ability to provide the full range of supervisory duties, which include responsibility for assignment of work, performance evaluations, selection of staff, and recommendation of awards, advancements, and disciplinary actions.

## **(9) Cytotechnologist (Regional Commissioner Technologist), GS-13**

- (a) **Experience.** At this level, the candidate must have one year of creditable experience equivalent to the next lower grade level that is directly related to the position to be filled.
- (b) **Assignments.** For all assignments above the journey level, the higher-level duties must consist of significant scope, complexity (difficulty), range of variety, and be performed by the incumbent at least 25% of the time. The

cytotechnologist (regional commissioner technologist) serves as an authority for multiple laboratories in a region to ensure compliance with inspection and accreditation requirements and regulations. The cytotechnologist (regional commissioner technologist) provides direction and guidance to resolve technical problems and provides interpretation of existing regulations. The cytotechnologist (regional commissioner technologist) coordinates with VHA Central Office to ensure that each testing site is in compliance with inspection and accreditation requirements and regulations. The cytotechnologist (regional commissioner technologist) assists laboratories in the correction of any cited inspection deficiencies. The cytotechnologist (regional commissioner technologist) is responsible for coordinating the CLIA license applications for all laboratories in the region. The cytotechnologist (regional commissioner technologist) serves as a consultant to national program officials and provides professional, technical, and training support. The cytotechnologist (regional commissioner technologist) requires verbal, written, and electronic communication with accrediting and regulatory bodies. The cytotechnologist (regional commissioner technologist) works under the direction and guidance of the VHA Office of Enforcement in VHA Central Office.

(c) **Demonstrated Knowledge, Skills, and Abilities.** In addition to the experience above, the candidate must demonstrate all of the following KSAs:

- i. Advanced knowledge of laboratory regulations that pertain to quality control, quality management, and proficiency testing, in order to assess and assist with laboratory compliance of quality programs in each facility assigned to that region.
- ii. Ability to differentiate and interpret accrediting and regulatory requirements to provide guidance to laboratories on regulatory requirements, and to assess compliance for each laboratory assigned to that region.
- iii. Knowledge of laboratory operations and the laboratory's role within the total organization.
- iv. Ability to create and deliver educational presentations to a variety of individuals, on matters that pertain to inspection and accreditation rules, regulations, and standards of all laboratory accrediting agencies.
- v. Knowledge of anatomic pathology, clinical laboratory, and ancillary testing.

(10) **Cytotechnologist (Laboratory Director), GS-14**

(a) **Experience and Education.** At this level, the candidate must possess one year of creditable experience equivalent at the GS-13 grade level that is directly related to the position to be filled. A candidate must hold a doctoral degree in

chemical, physical, biological, or clinical laboratory science from an accredited institution, be certified, and continue to be certified by a board approved by the Department of Health and Human Services.

(b) **Assignment.** For all assignments above the journey level, the higher-level duties must consist of significant scope, complexity (difficulty), range of variety, and be performed by the incumbent at least 25% of the time. The laboratory director is responsible for the overall operation and administration of the laboratory, in accordance with 42 Code of Federal Regulations (CFR) § 493. The laboratory director must ensure 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 laboratory director 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 laboratory director ensures the 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 laboratory director ensures that quality control and quality assessment programs are established and maintained, to provide quality services and identify failures in quality as they occur. The laboratory director ensures that 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 laboratory director ensures that consultation is available to the laboratory's clients on matters relating to the quality of the test results reported and their interpretation concerning specific patient conditions. The laboratory director ensures that a general supervisor provides on-site supervision of high complexity testing performed by an adequate number of testing personnel qualified under 42 CFR 493.1489.

(c) **Demonstrated Knowledge, Skills, and Abilities.** In addition to the experience above, the candidate must demonstrate all of the following KSAs:

- i. Expert knowledge of both clinical and anatomic pathology laboratory testing systems, test performance, and all phases of testing.
- ii. Expert knowledge of testing methodologies, policies, procedures, and quality assurance requirements to ensure accurate, reliable results, in compliance with the CFR and accrediting agency requirements.
- iii. Skill in identifying deviations from established performance requirements.

- iv. Ability to take remedial action to address performance deficiencies.
- v. Ability to provide leadership and administrative guidance to subordinate staff.
- vi. Ability to communicate effectively orally and in writing with a diverse group of professional staff and management officials at all levels.
- vii. Skill in use of and oversight of the LIS, program techniques, computer language, and program design.

## **7. DEVIATIONS**

- a. The approving official may, under unusual circumstances, approve reasonable deviations to the grade determination requirements for cytotechnologists in VHA whose composite record of accomplishments, performance, and qualifications, as well as current assignments, warrants such action based on demonstrated competence to meet the requirements of the proposed grade.
- b. Under no circumstances will the certification or educational requirements as a cytotechnologist be waived. The placement of individuals in grade levels not described in this standard must be approved by the Under Secretary for Health, or designee, in VHA Central Office.

**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)