Department of Veterans Affairs
Washington, DC 20420

VA HANDBOOK 5005/104
Transmittal Sheet
March 25, 2019

STAFFING

1. **REASON FOR ISSUE:** To revise the Department of Veterans Affairs (VA) qualification standard for the appointment of a Biomedical Engineer, GS-0858, appointed under the authority of 38 U.S.C. § 7401(3) and 38 U.S.C. § 7405 (a)(1)(B) in VA.

2. **SUMMARY OF CONTENTS/MAJOR CHANGES:** This handbook contains mandatory procedures on staffing. The pages in this issuance replace the corresponding page numbers in VA Handbook 5005/Staffing, Appendix G38. The revised standards are effective on the date of this publication; however, no action may be taken by the Human Resources Officer to convert or promote employees until training and guidance is received on the implementation on the standard. These changes will be incorporated into the electronic version of VA Handbook 5005 that is maintained on the Office of Human Resources Management Website. Significant changes include:

   a. Clarification of education requirements.

   b. Elimination of GS-5 entry level assignment.

   c. Change in the full performance level.

   d. Elimination of the supervisory assignment for the GS-12 grade level.

   e. Establishment of the first supervisory level at the GS-13 grade level.

   f. Update of knowledge, skills, and abilities at all levels for each assignment.

3. **RESPONSIBLE OFFICE:** Recruitment and Placement Policy Service (059), Office of the Deputy Assistant Secretary for Human Resources Management.

4. **RELATED DIRECTIVE:** VA Directive 5005, Staffing.

5. **RESCISSIONS:** None.

CERTIFIED BY:

/s/
Melissa S. Glynn, Ph.D.
Assistant Secretary for
Enterprise Integration

BY THE DIRECTION OF THE SECRETARY OF VETERANS AFFAIRS:

/s/
Daniel R. Sitterly
Assistant Secretary for
Human Resources and Administration/
Operations, Security and Preparedness

DISTRIBUTION: Electronic only

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

FORMER VA HANDBOOK REFERENCE: PART II APPENDIX G38
EFFECTIVE DATE: March 25, 2019

BIOMEDICAL ENGINEER
QUALIFICATION STANDARD
GS-0858
Veterans Health Administration

1. **COVERAGE.** This [qualification] standard applies to all [B]iomedical [E]ngineer, [GS-0858], positions in the Veterans Health Administration (VHA). The work requires the application of engineering concepts and methodology to investigate problems and phenomena of living systems, in order to advance the understanding of these systems and to improve medical practices. [In addition, the work involves the development and/or deployment of] materials, instruments, diagnostic and therapeutic devices, other equipment applicable to the study of living systems, and to the practice of medicine to improve healthcare delivery within [VHA. Biomedical Engineering work requires knowledge and skill in multiple engineering disciplines and specialized subject matter expertise in areas such as computer applications, electronics, mathematics, along with a background in human anatomy and physiology].

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

   b. **Approving Official**. The Assistant Deputy Under Secretary for Health (ADUSH) for

Administrative Operations, Veterans Integrated Service Network (VISN) Director, Facility Director, or designee is the approving official and will approve or disapprove the appointment or promotion of employees in hybrid occupations.

c. **Background Investigation.** Due to the sensitivity and criticality of systems managed by Biomedical Engineers, individuals may require higher than minimum background investigations based on the roles and responsibilities outlined in their Functional Statement. The Office of Personnel Management's Position Designation Automated Tool (PDAT) will be used to determine the appropriate investigation level.

d. **Certified Clinical Engineer (CCE)**. Certification means having successfully passed a CCE written and oral examination administered by the American College of Clinical Engineering. Individuals with CCE certification demonstrate competency and professional recognition, as measured by an examination designed by their peers. Certification promotes healthcare delivery improvement through the continuing assessment and recognition of the competency of professionals. These professionals support and advance patient care by applying engineering and management skills to healthcare technology. If appointed with a CCE requirement, the employee must maintain certification throughout employment. The American College of Clinical Engineering determines acceptable educational preparation and degree requirements for CCE eligibility.

e. **Creditable Professional Engineering Experience**. To be creditable, experience must have been accomplished after receipt of the bachelor's degree, and/or CCE certification, and requires the possession and use of knowledge, skills, and abilities associated within the scope of the biomedical engineering profession. Additionally, the experience must have been attained in a healthcare setting for Biomedical Engineer (Clinical) positions, or a research setting for Biomedical Engineer (Research) positions, and be directly applicable to the assignment.

f. **Foreign Education**. To be creditable for the education requirement, a degree/curriculum completed outside the U.S. must have been submitted to a private organization that specializes in the interpretation of foreign educational credentials. Such education must be, at a minimum, equivalent to a bachelor's degree, as outlined in Section 3.b. below.

g. **Lifecycle Management**. A Core Biomedical Engineering/Healthcare Technology Management function for medical equipment which includes: technology assessments, clinical/technical procurement specifications, equipment evaluations, pre-procurement planning, security configurations, deployment project management, technical configurations, ongoing maintenance/management/support, decommissioning, and cyber security sanitization.

h. **Part-Time Experience**. Part-time experience is creditable according to its relationship to the full-time work week. For example, one week of full-time credit is equivalent to two weeks of part-time work.]

4. BASIC REQUIREMENTS.

a. **Citizenship.** [Be] a citizen of the United States. (Non-citizens may be appointed when it is not possible to recruit qualified citizens in accordance with [VA Handbook 5005, Part II,] chapter 3, section A, paragraph 3.g.)

b. **Education and/or Experience**. [The individual must meet either item (1) or (2) below to meet this requirement:

(1) **Bachelor's Degree or Higher in Engineering**. To be creditable, the curriculum must be from a school of engineering with at least one curriculum accredited by the Accreditation Board for Engineering and Technology (ABET), as a professional engineering curriculum. Examples of acceptable engineering degrees include: Biomedical Engineering, Clinical Engineering, Bioengineering, Biomechanical Engineering, Electrical Engineering, Mechanical Engineering, and Biochemical Engineering. Titles may vary from educational institutions and change over time. **OR,**

(2) Certification as a Certified Clinical Engineer (CCE) and a bachelor's degree not listed in item 3.b.(1) above.]

c. **Grandfathering Provision**. All persons employed in VHA in this occupation, on the effective date of this qualification standard, are considered to have met all qualification requirements for the title, series and grade held, including positive education, and/or certification/registration that are part of the basic requirements of the occupation. For employees who do not meet all the basic requirements in this standard, but who met the qualifications applicable to the position at the time they were appointed to it, the following provisions apply:

(1) Such employees in an occupation that does not require a certification/registration, may be reassigned, promoted, or demoted within the occupation.

(2) 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.

(3) Employees initially grandfathered into this occupation, who subsequently obtain additional education and/or certification/registration, that meet all the basic requirements of this qualification standard, must maintain the required credentials as a condition of employment in the occupation.

(4) If an employee, who was retained in an occupation listed in 38 U.S.C. § 7401(3)

under this provision, leaves that occupation, the employee loses protected status, and must meet the full VA qualification standard requirements in effect at the time of reentry to the occupation.

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

e. **English Language Proficiency**. Biomedical Engineers must be proficient in spoken and written English in accordance with chapter 2, section D, paragraph 5a, this part.

[5.] GRADE REQUIREMENTS.

[ ]

[a.] **Grade Determinations**. In addition to the basic requirements for employment [listed in paragraph 3 above], the following education and experience criteria must be met when determining the grade of candidates:

[ ]

[(1) **Biomedical Engineer,] GS-7 [(Entry Level)]**

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

(b) **Education**. Bachelor's degree as outlined in paragraph 3.b.(1), above, or CCE certification with at least a bachelor's degree not listed in paragraph 3.b.(1).]

(c) **Demonstrated Knowledge, Skills, and Abilities [.** None beyond the basic requirements.

(d) **Assignment**. Employees serve in an entry level biomedical engineer career development position. It is expected that biomedical engineers at the entry level receive ongoing guidance from more experienced staff members and perform assignments under close supervision.]

(2) [**Biomedical Engineer,] GS-9 [(Developmental Level 1)]**

(a) **Experience**. At least [one] year of specialized experience equivalent to the next lower level.

OR,

(b) **Education**

i. [Master's degree in Biomedical Engineering, or a related field of study, as outlined in paragraph 3.b.(1).

OR,

ii. Bachelor's degree, as outlined in paragraph 3.b.(1), plus two full years of progressively higher level graduate education in a related field of study, that demonstrates the KSAs for the GS-9 level assignment.]

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

i. Knowledge of the principles, theories, concepts, and practices of the Biomedical Engineering profession.

ii. [Ability to interpret relevant codes, regulations, guidelines, and standards, and make recommendations to ensure compliance with medical center programs.

iii. Ability to understand the operational needs of clinical services in the health care system.

iv. Ability to prepare material on current technical topics and trends, for presentation to other technical staff and mid-level hospital management, and the ability to keep abreast of changes in technology.

(d) **Assignment.** Biomedical Engineers, at this developmental level, require direction on more complex tasks. Employees complete technical assignments in the engineering field, under the direction of a senior biomedical engineer and will be required to rotate through, and participate in, the operations of other hospital services. At the GS-9 grade level, employees function with oversight by a supervisor for more complex assignments.]

(3) **[Biomedical Engineer,] GS-11 [(Developmental Level 2)]**

(a) **Experience**. At least [one] year of experience equivalent to the next lower level, [and must fully meet the KSAs at that level.]

OR,

(b) **Education**

i. [Ph.D., or equivalent doctoral degree in Biomedical Engineering, or a related field of engineering, as outlined in paragraph 3.b.(1).

OR,

ii. Bachelor's degree, plus three full years of progressively higher level graduate education in a related field of study, as outlined in paragraph

3.b.(1).]

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

i. Ability to implement and/or sustain an equipment management or biomedical research program that meets The Joint Commission (TJC), National Fire Protection Association (NFPA), or other applicable regulatory requirements.]

ii. Ability to develop material for a continuing education program for clinical or research staff, that address the principles and application of medical technology, and/or biomedical theory used in healthcare.

iii. Ability to advise [ ] staff on emerging medical [ ] technology[, or research procedures], while keeping abreast of changes in such technology, and utilizing the information to solve biomedical engineering problems.

iv. [Knowledge of basic project management principles, as applied to the healthcare setting and medical equipment, and information system implementation.]

(d) **Assignment**. [At the developmental level, employees function on a semi-independent basis with limited oversight by senior biomedical engineers. They participate in medical device hazard investigations, to assure compliance with patient safety goals, the Safe Medical Devices Act (SMDA), TJC requirements, and assist in the development of an equipment management program at the medical center. Employees may lead medical technology deployments, directly support medical equipment, or participate in research projects.]

(4) [**Biomedical Engineer,] GS-12 [(Full Performance Level)]**

(a) **Experience.** Completion of at least [one] year of specialized experience equivalent to the next lower level; or completion of a post-doctoral research fellowship in the field of biomedical engineering, and must fully meet the KSAs at that level.

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

i. Ability to conduct a medical equipment management [or biomedical research program that is compliant with applicable healthcare standards and regulatory agencies.]

ii. Ability to develop a curriculum for a continuing education program, that

address the safe and effective use of medical technology, and/or research devices.

iii. Ability to manage a recall and safety alert program for medical devices, including medical device hazard investigations, to assure compliance with patient safety goals, SMDA, and [TJC] requirements.

[iv. Ability to conduct capital asset and infrastructure planning for medical equipment spanning initial concept, installation, and effective implementation of complex medical equipment.

v. Ability to function as the subject matter expert in the field of biomedical engineering, directly supporting specialized clinical technology, including service, system administration, training, quality assurance, and life-cycle management.

vi. Ability to effectively advise clinical and administrative staff on medical technology, including existing and emerging technology, which addresses viability, long-term suitability, compatibility, and/or safety.

vii. Knowledge of concepts related to computer based medical systems, networking protocols, and information security as it applies to medical technology within VHA.

viii. Skill in communicating and working collaboratively with key stakeholders, including technical and professional staff at various levels of the organization.

ix. Ability to apply project management principles to deployment of medical equipment and health information technologies.

(c) **Assignment.** At the full performance level, employees work under general supervision, with wide latitude to exercise independent judgment. Drawing upon extended professional and technical experience, employees demonstrate an intimate understanding of complex clinical and biomedical subject matter. They serve as institutional resources, working extensively with clinical stakeholders, supporting clinical services by leading market research, technology assessments, integration planning, and implementation of both current and emerging medical technologies. The employee shares responsibility for managing the Health Insurance Portability and Accountability Act (HIPAA), network security issues for medical systems, and the information communicated across these systems. Biomedical Engineers at the GS-12 grade level further support the clinical mission by contributing to the continuing education program for clinical staff, helping ensure safe and efficient healthcare delivery. Biomedical Engineers at the GS-12 grade level support the institution by assisting with capital asset and

infrastructure planning, to help ensure successful strategic planning. They may collaborate frequently with contracting to execute judicious healthcare technology procurements. Within the Biomedical Engineering Department, the employee provides leadership that ensures high quality and responsive customer service is an integral component of biomedical engineering service delivery. They are highly effective communicators, capable of serving as subject matter experts directly supporting the life cycle management of clinical technology, to include ongoing service, system administration, training, and quality assurance. At this level, employees may assist in clinical research projects in the biomedical engineering field.]

(5) [**Biomedical Engineer, (Clinical), GS-13]**

(a) **Experience**. Completion of at least one year of experience equivalent to the next lower level, and must be fully meet the KSAs at that level. Including:

i. Ability to implement and/or sustain an equipment management or biomedical research program that meets The Joint Commission (TJC), National Fire Protection Association (NFPA), or other applicable regulatory requirements.]

ii. Ability to develop material for a continuing education program for clinical or research staff, that address the principles and application of medical technology, and/or biomedical theory used in healthcare.

iii. Ability to advise [ ] staff on emerging medical [ ] technology[, or research procedures], while keeping abreast of changes in such technology, and utilizing the information to solve biomedical engineering problems.

iv. [Knowledge of basic project management principles, as applied to the healthcare setting and medical equipment, and information system implementation.]

(b) **Demonstrated Knowledge, Skills, and Abilities.** [In addition to the experience above, the candidate must demonstrate all of the following KSAs. In addition, the candidate must demonstrate the following KSAs found at subparagraph (b) of this subsection (5) and potential to acquire the assignment specific KSAs designated by an asterisk (*).]

i. Ability to conduct capital asset and infrastructure planning for medical equipment spanning initial concept, installation, and effective implementation of complex medical equipment.

ii. *Knowledge [and capacity to support the most complex and specialized clinical technology including service, system administration, training, and quality assurance.]

iii. [K]nowledge of, and the ability to interpret and apply complex codes, regulations, guidelines, and standards associated with the biomedical engineering field.

iv. [Ability to develop and implement policies that are consistent with organizational objectives.

v. Ability to communicate and work collaboratively with key stakeholders, including technical and professional staff at various levels of the organization.

(c) **Assignment**. For all assignments above the full performance 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 this level, employees are non- supervisory, and are organizationally aligned at the facility, Regional, VISN, or National Program Offices. At the facility level, employees must have notable ongoing responsibilities as assigned by the VISN, and/or Healthcare Technology Management Program Office. The employee supports and advances patient care by applying engineering and managerial skills to healthcare technology, as demonstrated by at least four of the following major responsibilities:

i. Assures provision of a continuing education program for clinical or technical staff, addressing the principles and application of healthcare technology used in the delivery of care. This includes a curriculum that addresses the safe and effective use of medical equipment and/or technology.

ii. Manages a recall and safety alert program for medical devices, including medical device incident investigations, to assure compliance with patient safety goals, SMDA, and TJC requirements.

iii. Serves as advisor to senior clinical and leadership staff on medical engineering technology (including existing and emerging technology), addressing viability, long-term suitability, compatibility, and/or safety for strategic initiatives.

iv. Conducts capital asset and infrastructure planning for medical technology spanning initial concept, installation, and effective implementation of highly complex medical technology. Responsible for life-cycle management for medical technology across the scope of a facility or VISN.

v. Serves as a VISN or national expert, who provides support of one or more complex, multi-site systems, to include service, system administration, training, and quality assurance.

vi. Responsible for a medical equipment management program that meets

current TJC and NFPA hospital requirements.

vii. Develops and implements VISN or national-level policies that are consistent with Healthcare Technology Management Program Office organizational objectives.

(6) **Supervisory Biomedical Engineer (Clinical), GS-13**

(a) **Experience.** Completion of at least one year of experience equivalent to the next lower level, and must fully meet the KSAs at that level.

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

i. Knowledge of the management of overall department resources, i.e., finances, space, equipment, supplies, and staffing at the local level.

ii. Ability to draft and/or recommend local policies and/or directives related to healthcare technology management.

iii. Ability to balance multiple responsibilities, set priorities, delegate tasks, meet multiple deadlines, analyze organizational problems, and develop and implement effective solutions.

iv. Ability to analyze organizational and operational problems to develop and implement solutions that result in efficient operations, and use data effectively to manage workload, quality, performance, and productivity within the area of responsibility.

v. Skill in interpersonal relationships in leading and dealing with employees, team leaders, and managers, both within and outside the biomedical engineering program, to include conflict management, dispute resolution, mediation, or reasonable accommodations.

(c) **Assignment**. For all assignments above the full performance 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 this level, employees are supervisors and are at the facility level. The supervisory biomedical engineer (clinical) is responsible for the professional and administrative management of a facility biomedical engineering program. Such individuals have responsibility supervising technical staff, including lower level engineers, biomedical engineering technicians, and other staff. The range of supervisory responsibility includes development of performance standards and performance evaluations; recommendations for appointments, awards, advancements, and when appropriate, disciplinary actions; and identification of

continuing training needs etc. The supervisory biomedical engineer (clinical) is responsible for financial management of budget resources allocated to support quality assurance and maintenance activities necessary to assure the facility's medical equipment is available for patient care activities. The supervisory biomedical engineer (clinical) is responsible for compliance and reporting of medical device cyber security and isolation for facilities under their management oversight.

(7) **Biomedical Engineer (Research), GS-13**

(a) [**Experience.** Completion of at least one year of experience equivalent to the next lower level and must fully meet the KSAs at that level.

(b) **Demonstrated Knowledge, Skills, and Abilities.** In addition to the experience above, the biomedical engineer (research) must demonstrate all of the following KSAs:

i. Ability to apply appropriate scientific methods in the design and execution of basic and applied research in the field of biomedical engineering.

ii. Ability to coordinate work across multiple settings, e.g., medical centers, universities.

iii. Ability to convey scientific biomedical engineering concepts and methodology to individuals with various levels of technical expertise.

(c) **Assignment**. The biomedical engineer (research) is responsible for conducting biomedical research involving significant engineering concepts and applications as an investigator; serving as senior author in the preparation of manuscripts published in peer-reviewed archival journals; serving as principal investigator on competitive research proposals for funding by Federal and non-Federal peer reviewed sources; disseminating research findings at the local facility, and interacting with clinicians and clinical biomedical engineers.

(8) **Biomedical Engineer (Clinical), GS-14]**

(a) **Experience.** Completion of at least [one] year of experience equivalent to the next lower level, and must fully meet the KSAs at that level.

(b) **Demonstrated Knowledge, Skills, and Abilities**[. In addition to the experience above, the biomedical engineer (clinical) must demonstrate all of the following KSAs. In addition, the candidate must demonstrate the potential to acquire the assignment specific KSAs designated by an asterisk (*):]

i. [*][Ability to apply advanced knowledge of relevant codes, regulations, guidelines, and standards associated with biomedical engineering to support the needs of multiple facilities.

ii. Ability to effectively convey highly technical information to] a wide variety of individuals, including technical and professional clinical staff, and senior level managers at the facility, VISN and/or national level.

iii. *Ability to manage a recall and safety alert program for medical devices, including medical device incident investigations to assure compliance with patient safety goals, SMDA, and [TJC requirements for multiple facilities.]

iv. [ ] Ability to apply advanced knowledge of principles, theories, concepts, and practices of biomedical engineering. This would include the ability to keep abreast of changes in technology and utilize the information gained in the solution of biomedical engineering problems to meet operational needs of multiple facilities.

v. *Ability to directly support the most complex and specialized clinical technology including service, system administration, training, and quality assurance for multiple facilities.

vi. [*Ability to work collaboratively with other disciplines, senior management, VHA Central Office, and VISN staff.

vii. Ability to develop and implement healthcare technology management policies that are consistent with organizational objectives. Scope of organization spans from multiple facilities to national.

(c) **Assignment**. For all assignments above the full performance 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 this level, employees are non-supervisory and are typically at the VISN or National Program Offices. At the VISN level, employees must have notable ongoing responsibilities, as assigned by the VISN and/or Healthcare Technology Management Program Office. Major duties must include at least four of the following major responsibilities:

i. Supports and advances patient care by applying engineering and managerial skills to healthcare technology across the VISN, or nationally.

ii. Assists and advises facilities in the implementation of an equipment management program that meets current TJC and NFPA requirements. Evaluates other biomedical engineering programs in the VISN or the national program office.

iii. Assures provision of a continuing education program for professional staff addressing the principles and application of healthcare technology management. This includes a curriculum that addresses the safe and effective management of medical equipment and/or technology. Provides continuing education on behalf of the VISN and/or the national program office.

iv. Provides support and oversight for a recall and safety alert program for medical devices in the VISN, or for the national program office, including medical device incident investigations, to ensure compliance with patient safety goals, SMDA, and TJC requirements. Conducts medical equipment investigations for the VISN or the national program office.

v. Serves as a subject matter expert advisor to senior VISN or national clinical and leadership staff on medical technology crossing multiple clinical disciplines, including existing and emerging technology, addressing viability, long-term suitability, compatibility, and/or safety.

vi. Conducts and/or supports capital asset and infrastructure planning of medical technology found in a hospital, spanning initial concept, installation, and effective implementation of complex medical equipment.

vii. Implementation of complex medical technology. Participates in capital asset planning at the VISN and/or national level. Analyzes organizational and operational problems and develops timely and economical solutions to meet facility, VISN, and/or national needs.

viii. Serves as an institutional expert supporting the most complex and specialized clinical technology, including service, system administration, training, sustainment, and quality assurance across multiple facilities.

ix. Develops national policy for the Healthcare Technology Management Program Office. Serves as a senior technology advisor to assist the Healthcare Technology Management Program Office with technology and program management.

(9) **Supervisory Biomedical Engineer (Clinical), GS-14**

(a) **Experience.** Completion of at least one year of experience equivalent to the next lower level, and must fully meet the KSAs at that level.

(b) **Demonstrated Knowledge, Skills, and Abilities.** In addition to the experience above, the biomedical engineer (clinical) must demonstrate all of the following KSAs:

i. Ability to manage overall department resources, i.e., finance, space,

equipment, supplies, and staffing at a highly complex medical center or at the VISN level.

ii. Ability to develop local or VISN policies and/or draft directives related to healthcare technology management.

iii. Skill in balancing multiple responsibilities, setting priorities, delegating tasks and projects, meeting multiple deadlines, analyzing organizational problems, and developing and implementing effective solutions.

iv. Ability to analyze complex organizational and operational problems to develop and implement solutions that result in efficient operations, and use data effectively to manage workload, quality, performance, and productivity within the area of responsibility.

v. Skill in interpersonal relationships leading and dealing with employees, team leaders, and managers, within and outside the biomedical engineering program, to include conflict management, dispute resolution, mediation, or reasonable accommodations.

(c) **Assignment**. For all assignments above the full performance 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 this level, employees are supervisors and are at the facility, VISN, or National Program Office level. The supervisory biomedical engineer (clinical) is assigned overall biomedical engineering program management responsibility typically found at a university affiliated tertiary care facility (complexity level 1,) with one or more subordinate biomedical engineers. In this assignment, supervisory biomedical engineers at the facility level will have notable ongoing responsibilities, supporting VISN biomedical engineering initiatives, and/or notable ongoing responsibilities as assigned by the Healthcare Technology Management (HTM) Program Office. The range of supervisory responsibility includes development of performance standards and performance evaluations; recommendations for appointment; awards; advancements; and when appropriate, disciplinary actions and identification of continuing training needs, etc. At this level, the supervisor is responsible for the financial management of budget resources allocated to support quality assurance and maintenance/management activities necessary to assure the facility medical equipment inventory is available for patient care activities. The supervisory biomedical engineer (clinical) is responsible for compliance and reporting of medical device, cyber security, and isolation for facilities under their management oversight.

OR,

At the VISN level, the supervisory biomedical engineer (clinical) is responsible for oversight and coordination of facility biomedical engineering programs, and will serve as the primary liaison between the HTM Program Office and the VISN and facilities. The supervisory biomedical engineer (clinical) must have notable ongoing responsibilities, as assigned by the HTM Program Office. The supervisory biomedical engineer (clinical) is responsible for compliance and reporting of medical device security and isolation for facilities under their management oversight.

OR,

At the national level, the supervisory biomedical engineer (clinical) is assigned responsibility for specific program areas within the HTM Program Office.

(10) **Biomedical Engineer (Research), GS-14**

(a) **Experience.** Completion of at least one year of experience equivalent to the next lower level and must fully meet the KSAs at that level.

(b) **Demonstrated Knowledge, Skills, and Abilities.** In addition to the experience above, the biomedical engineer (research) must demonstrate the following KSAs and potential to acquire the assignment specific KSAs designated by an asterisk (*):

i.] Ability to provide formal clinical, research, and/or educational consultation to multidisciplinary staff.

[ii.] Knowledge of the legal, ethical, and professional standards applicable to clinical research in the field of biomedical engineering.

*[iii.] Knowledge of budget control procedures that including funding from multiple sources and may vary annually.

[(c) **Assignment**. At this level, the biomedical engineer (research) designs and supervises biomedical research projects, including the assembly and supervision of an investigative team; has a record of publication as a senior author on manuscripts published in peer-reviewed archival journals; participates in the peer-review of manuscripts in archival journals; has a record of funded, competitive research proposals by Federal or non-Federal peer-reviewed sources; disseminates research findings at the VISN, national, and international level; and participates in the mentorship and training of junior researchers and investigators.]

(11)[**Supervisory Biomedical Engineer (Clinical), GS-15**

(a) **Experience.** Completion of at least one year of experience equivalent to the next lower level and must fully meet the KSAs at that level.

(b) **Demonstrated Knowledge, Skills, and Abilities.** In addition to the experience above, the biomedical engineer (research) must demonstrate the following KSAs and potential to acquire the assignment specific KSAs designated by an asterisk (*) below:

i. Ability to balance responsibilities in an extremely complex environment and to work with great autonomy.

*ii. Ability to independently create, organize, manage, and maintain high-quality programs.

iii. Knowledge of budget control procedures that include funding from multiple sources, which may vary annually.

iv. Ability to interpret and apply relevant codes, regulations, guidelines, and standards associated with biomedical engineering to establish criteria on a national basis for biomedical engineering programs across VHA.

v. Ability to effectively communicate technical information with a wide variety of individuals, including senior VHA executives at the VACO level.

vi. Ability to apply the principles, theories, concepts, and practices of the biomedical engineering profession to establish guidance and national policies.

vii. Knowledge of, and experience in conducting medical equipment investigations or biomedical engineering program reviews for the National Program Office.

(c) **Assignment.** The Under Secretary for Health, or designee, may approve the assignment of a biomedical engineer at the GS-15 grade level when the composite record of qualifications, scope, and complexity of the assignment justifies such action. At this level, employees may be in supervisory or research positions. Other positions may be established when the composite record of qualifications, scope, and complexity of the assignment justifies such action. For all assignments above the full performance 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.

Within this assignment, the GS-15 grade level is for the Director and the senior program manager within the VHA HTM Program Office, as well as VISN biomedical engineers with full programmatic responsibility (staffing, budget,

planning, compliance, etc.) over all facility biomedical engineering programs within their VISN. On a limited basis, VISN biomedical engineers with notable, ongoing national responsibilities, a composite record of qualifications and accomplishments, and HTM Program Office leadership will qualify. The supervisory biomedical engineer (clinical) supports and advances patient care by applying engineering and managerial skills to healthcare technology, as demonstrated by at least four of the following major responsibilities:

i. Establishes national criteria for VHA's medical equipment management program that meet current TJC, NFPA, and VA standards. Responsibility at this level would typically be held by the Director or Associate Director of the HTM Program Office.

ii. Manages a VISN biomedical engineering program with direct management/supervisory responsibilities over all facility biomedical engineering programs.

iii. Serves as a national subject matter expert for the HTM Program Office in one or more.

iv. core competency or programmatic areas for biomedical engineering and has notable ongoing.

v. responsibility in the area, in support of the National Program Office.

vi. Assures provision of a continuing education program for professional staff addressing the principles and application of medical instrumentation used in the delivery of healthcare. This includes a curriculum that addresses the safe and effective use of medical equipment and/or technology. Develops and organizes training for the VISN or national level for professional engineering, and medical staff as appropriate on engineering topics.

vii. Leads high profile medical equipment investigations or program reviews for the VHA HTM Program Office.

viii. Works with the full range of clinical programs at the national level to identify medical equipment needs and priorities, determines maintenance, support, and quality assurance requirements. Serves as an expert technical advisor to senior clinical and HTM staff on medical technology (including existing and emerging technology), for multiple sites addressing viability, long-term suitability, compatibility, and/or safety. Leads technology assessment activities for the VHA HTM Program Office.

ix. Represents VHA capital asset and infrastructure planning for medical equipment at the national level. Reviews all requests for major medical equipment systems to assure they meet economic and programmatic

requirements established by VA and good clinical practice; or coordinates VISN requests for major medical equipment systems to assure they meet VISN economic and programmatic requirements; and assists with capital asset review at the national level.

(12) **Biomedical Engineer (Research), GS-15**

[(a) **Experience**. Completion of at least one year of experience equivalent to the next lower level and must fully meet the KSAs at that level.

(b) **Demonstrated Knowledge, Skills, and Abilities.** In addition to the experience above, the biomedical engineer (research) must demonstrate the following KSAs and potential to acquire the assignment specific KSAs designated by an asterisk (*):]

[i.] Ability to balance responsibilities in an extremely complex environment and to work with great autonomy.

[*ii.] Ability to independently create, organize, manage, and maintain high-quality programs.

[iii.] Knowledge of budget control procedures that include funding from multiple sources which may vary annually.

[(c) **Assignment.** At this level the biomedical engineer (research) assembles, maintains, and guides broad-based research efforts involving multiple independently funded investigators; maintains a competitive publication record achieving national and/or international recognition for research accomplishments; serves as a principal investigator on multiple research projects funded by Federal and/or non-Federal sources; serves as a principal investigator on programs or center research proposals for funding by Federal or non-Federal peer-reviewed sources; designs and supervises a mentoring and career development program for junior researchers and investigators; participates in editorial decisions, or serves on the editorial board of an archival journal, and/or is involved in research grant proposal peer-review, and/or in regional or national research policy development. An employee achieving the academic rank at the full professor level, at an affiliated university's promotion and tenure committee, may demonstrate this recognition.

6.] DEVIATIONS.

a. The appointing official may, under unusual circumstances, approve reasonable deviations to the grade determination requirements for Biomedical Engineers in VHA whose composite record of accomplishments, performance, and qualifications, as well as current assignments, warrant such action based on demonstrated competence to

meet the requirements of the proposed grade.

b. 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)