APPENDIX G38. BIOMEDICAL ENGINEER QUALIFICATION STANDARD

GS-858
Veterans Health Administration

1. COVERAGE. This standard applies to all biomedical engineer 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 to advance the understanding of these systems and improve medical practices; to develop materials, instruments, diagnostic and therapeutic devices, and other equipment applicable in the study of life systems and the practice of medicine; and to improve health service delivery systems for communities and within individual VA facilities (medical centers, outpatient clinics, domiciliaries). Biomedical engineering work requires, in addition to knowledge and skill in engineering disciplines, a background in physiology and anatomy, and a practical facility in specialized subject matter areas such as computer applications, electronics, or mathematics.

2. BASIC REQUIREMENTS

   a. Citizenship. Citizen of the United States. (Non-citizens may be appointed when it is not possible to recruit qualified citizens in accordance with chapter 3, section A, paragraph 3g, this part.)

   b. Education and/or Experience

      (1) Bachelor’s degree: Professional engineering. To be acceptable, the curriculum must: (a) Be in a school of engineering with at least 1 curriculum accredited by the Accreditation Board for Engineering and Technology (ABET) as a professional engineering curriculum; or, (b) Include differential and integral calculus, and courses (more advanced than first-year physics and chemistry) in 5 of the following 7 areas of engineering science or physics: (1) statics and/or dynamics; (2) strength of materials (stress-strain relationships); (3) fluid mechanics and/or hydraulics; (4) thermodynamics; (5) electrical fields and circuits; (6) nature and properties of materials (relating particle and aggregate structure to properties); or (7) any other comparable area of fundamental engineering science or physics, such as optics, heat transfer, soil mechanics, or electronics.

      OR,

      (2) Combination of education and experience: College-level education, training, and/or technical experience that furnished: [a] a thorough knowledge of the physical and mathematical sciences underlying professional engineering; and [b] a good understanding, both theoretical and practical, of the engineering sciences and techniques and their applications to 1 of the branches of engineering. The adequacy of such background must be demonstrated by 1 of the following:

         1. Professional registration: Current registration as a professional engineer by any State, Territory, Commonwealth of the United States (e.g., Puerto Rico), or the District of Columbia. Absent other means of qualifying under this standard, those applicants who achieved such registration by means other than a written test (e.g., State grandfather or eminence provisions) are eligible only for positions that are within or closely related to the specialty field of their registration. For example, an applicant who attains registration through a State board’s eminence provision as a manufacturing engineer typically would not be rated eligible for biomedical engineering positions.
2. **Written Test:** Evidence of having successfully passed the Engineer-in-Training (EIT) examination, or the written test required for professional registration, which is administered by the Boards of Engineering Examiners of a State, Territory, Commonwealth of the United States (e.g., Puerto Rico), or the District of Columbia.

Applicants who have passed the EIT examination and have completed all the requirements for either [a] a bachelor's degree in engineering technology (BET) from an accredited college of university that included 60 semester hours of courses in the physical, mathematical, and engineering sciences, OR, [b] a BET from a program accredited by the Accreditation Board for Engineering and Technology (ABET) may be rated eligible for certain engineering positions at GS-5. Eligibility is limited to positions that are within, or closely related to, the specialty field of the engineering technology program. Applicants for positions that involve highly technical research, development, or similar functions requiring an advanced level of competence in basic science must meet the basic requirements in paragraph 2.b.(1).

Because of the diversity in kind and quality of BET programs, graduates of other BET programs are required to complete at least 1 year of additional education or highly technical work experience of such nature as to provide reasonable assurance of the possession of the knowledge, skills, and abilities required for professional engineering competence. The adequacy of this background must be demonstrated by passing the EIT examination.

3. **Specified academic courses:** Successful completion of at least 60 semester hours of courses in the physical, mathematical, and engineering sciences and in engineering that included the courses specified in the basic requirements. The courses must be fully acceptable toward meeting the requirements of a professional engineering curriculum as described in paragraph 2.b(1).

4. **Related curriculum.** Successful completion of a curriculum leading to a bachelor's degree in engineering technology or in an appropriate professional field, e.g., physics, chemistry, architecture, computer science, mathematics, hydrology, or geology, may be accepted in lieu of a degree in engineering, provided the applicant has had at least 1 year of professional engineering experience acquired under professional engineering supervision and guidance. Ordinarily, there should be either an established plan of intensive training to develop professional engineering competence, or several years of prior professional engineering-type experience, e.g., in interdisciplinary positions. (The above examples of related curricula are not all-inclusive.)

c. **Grandfathering Provision.** The following is the standard grandfathering policy for all Title 38 hybrid qualification standards. Some of these provisions may not apply to this occupation. Please carefully review the qualification standard to determine the specific education and/or licensure/certification/registration requirements that apply to this occupation.

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 licensure/certification/registration that are part of the basic requirements of the occupation. For employees who do not meet all the basic requirements required in this standard, but who met the qualifications applicable to the position at the time they were appointed to it, the following provisions apply:
Such employees in an occupation that does not require a licensure/certification/registration, may be reassigned, promoted, or demoted within the occupation.

Such employees in an occupation that requires a licensure/certification/registration, may be reassigned, promoted up to and including the full performance (journey) level, or demoted within the occupation, but may not be promoted beyond the journey level or placed in supervisory or managerial positions.

Such employees in an occupation that requires a licensure/certification/registration only at higher grade levels must meet the licensure/certification/registration requirement before they can be promoted to those higher grade levels.

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.

Employees initially grandfathered into this occupation, who subsequently obtain additional education and/or licensure/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.

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.


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.

3. **GRADE REQUIREMENTS**

a. **Definitions**

   (1) **Professional Engineering Experience**

   (a) Professional knowledge of engineering is defined as the comprehensive, in depth, knowledge of mathematical, physical, and engineering sciences applicable to a specialty field of engineering that characterizes a full 4-year professional engineering curriculum leading to a bachelor's degree, or the equivalent.

   (b) Professional ability to apply engineering knowledge is defined as the ability to:

   1. Apply fundamental and diversified professional engineering concepts, theories, and practices to achieve engineering objectives with versatility, judgment, and perception;

   2. Adapt and apply methods and techniques of related scientific disciplines; and
3. Organize, analyze, interpret, and evaluate scientific data in the solution of engineering problems.

(2) **Part-time Experience.** Part-time experience as a professional biomedical engineer is credited according to its relationship to a full-time workweek. For example, a biomedical engineer would receive 1 week of full-time credit for each 2 weeks of half-time work.

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

(1) **GS-5**

(a) **Experience.** None beyond the basic requirements. Meeting these requirements should demonstrate the following:

(b) **Demonstrated Knowledge, Skills, and Abilities**

1. Knowledge of, and ability to apply, the principles, theories, concepts, and practices of the engineering profession.

2. Skill to effectively communicate both orally and in writing with a wide variety of individuals, including communicating highly technical information.

3. Knowledge of, and ability to interpret and apply, relevant codes, regulations, guidelines, and standards associated with engineering.

4. Ability to analyze organizational and operational problems and develop timely and economical solutions.

5. Ability to keep abreast of changes in technology and to utilize information gained in the solution of engineering problems.

(c) **Assignment.** Employees at this grade level serve in career development positions.

(2) **GS-7**

(a) **Experience.** In addition to the basic requirements, 1 year of experience equivalent to the next lower level. In addition, the candidate must demonstrate the following KSAs:

OR,

(b) **Advanced Entry Level Placement.** See VA Handbook 5005, Appendix G17.

(c) **Demonstrated Knowledge, Skills, and Abilities**

1. Ability to prepare written and graphic presentations for other technical staff including technicians and other junior engineers.
2. Knowledge of relevant codes, regulations, guidelines, and standards.

3. Ability to learn organizational concepts to meet operational needs.

4. Ability to learn new technology and identify changes and trends for presentation to other technical staff.

(d) **Assignment.** Employees at this level are in career development positions with the close supervision of higher-level biomedical engineers.

(3) **GS-9**

(a) **Experience.** At least 1 year of specialized experience equivalent to the next lower level. In addition, the candidate must demonstrate the following KSAs:

**OR,**

(b) **Education.** Education equivalent to 2 full years of progressively higher level graduate education or master’s or equivalent graduate degree in a field of engineering, e.g., biomedical engineering, general engineering, mechanical engineering, etc., provided the applicant’s total background demonstrates the core competencies for GS-9 level assignment.

(c) **Demonstrated Knowledge, Skills, and Abilities**

1. Knowledge of the principles, theories, concepts, and practices of the biomedical engineering profession.

2. Knowledge of relevant codes, regulations, guidelines, and standards, and the ability to make recommendations to assure compliance with medical center programs.

3. Knowledge of organizational concepts and an understanding of the operational needs of other administrative hospital services.

4. 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.** Employees at this level complete technical assignments in the engineering field as assigned by senior engineers, and will be required to rotate through, and participate in, the operations of other administrative hospital services. At the GS-9 level, employees will function at a more independent level with oversight by a supervisor for more complex assignments.

(4) **GS-11**

(a) **Experience.** At least 1 year of experience equivalent to the next lower level. In addition, the candidate must demonstrate the following KSAs:
OR,

(b) Education. Three full years of progressively higher-level graduate education or a Ph.D. or equivalent doctoral degree in biomedical engineering or a related engineering field, provided the applicant’s total background demonstrates evidence of knowledge, skills, and abilities necessary to perform the work of the position to be filled.

(c) Demonstrated Knowledge, Skills, and Abilities

1. Knowledge of an equipment management program that meets current Joint Commission on the Accreditation of Health Care Organizations (JCAHO) and National Fire Protection Association (NFPA) requirements.

2. Ability to develop material for a continuing education program for clinical staff that addresses the principles and application of medical instrumentation used in the delivery of healthcare.

3. Ability to advise clinical and administrative staff on emerging medical engineering technology, while keeping abreast of changes in such technology, and utilizing the information to solve biomedical engineering problems.

(d) Assignment. At this level, employees will function on an independent basis at the full performance level; will participate in medical device hazard investigations to assure compliance with patient safety goals, the Safe Medical Devices Act (SMDA), and JCAHO requirements; and will assist in the development of an equipment management program at the medical center. At this level, employees may assist in clinical research projects in the biomedical engineering field.

(5) GS-12

(a) Experience. Completion of at least 1 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. In addition, the candidate must demonstrate the following professional KSAs and demonstrate the potential to acquire the assignment specific KSAs designated by an asterisk (*):

(b) Demonstrated Knowledge, Skills, and Abilities

*1. Ability to conduct an equipment management program that meets current JCAHO and NFPA requirements.

*2. Ability to develop a curriculum for a continuing education program that addresses the safe and effective use of medical equipment and/or technology.

*3. 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 JCAHO requirements.
4. Skill in advising clinical and administrative staff on medical engineering technology, including existing and emerging technology and which addresses viability, long-term suitability, compatibility, and/or safety.

5. Ability to analyze organizational and operational problems and recommend timely and economical solutions involving medical equipment spanning initial concept, installation, and effective implementation of complex medical equipment.

(d) **Assignment.** At this level, employees may be in non-supervisory or supervisory positions. For all assignments above the full performance level, the higher-level duties must consist of significant scope, complexity (difficulty), and range of variety, and be performed by the incumbent at least 25% of the time.

1. **Biomedical Engineer (Clinical).** Non-supervisory employees support and advance patient care by applying engineering and managerial skills to healthcare technology as demonstrated by at least 3 of the following major responsibilities:

   a. Conducting an equipment management program that meets current JCAHO and NFPA requirements. The breadth of technology is less than is typically present at a tertiary care and/or university-affiliated institution.

   b. Assuring the provision of a continuing education program for clinical staff addressing the principles and application of medical instrumentation used in the delivery of healthcare. This requires skill to effectively communicate, both orally and in writing, with a wide variety of individuals, including technical and professional clinical staff, to communicate technical information.

   c. Managing a recall and safety alert program for medical devices, including medical device incident investigations to assure compliance with patient safety goals, SMDA, and JCAHO requirements.

   d. Advising clinical and administrative staff on medical engineering technology including existing and emerging technology addressing viability, long-term suitability, compatibility, and/or safety while keeping abreast of changes in technology and utilizing information gained in the solution of biomedical engineering problems.

   e. Assisting with capital asset and infrastructure planning for medical equipment spanning initial concept, installation, and effective implementation of complex medical equipment.

   f. Functioning as the subject matter expert in the field of biomedical engineering who directly supports specialized clinical technology including service, system administration, training, and quality assurance at a medical center.

2. **Supervisory Biomedical Engineer.** The supervisory biomedical engineer is responsible for the professional and administrative management of a biomedical engineering section in a facility with complexity equal to a secondary care facility. Such individuals typically have responsibility for 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 is responsible for financial management of budget resources allocated to support quality assurance, and maintenance activities necessary to assure the facility medical equipment inventory is available for patient care activities. In addition to the core competencies for GS-12 level positions, the candidate must demonstrate the following professional KSAs and demonstrate the potential to acquire the assignment specific KSAs designated by an asterisk (*):

a. Ability to organize work, set priorities, delegate tasks, and meet multiple deadlines.

b. Skill in managing and directing the work of others to accomplish programs goals and objectives.

c. Ability to translate management goals and objectives into well-coordinated and controlled biomedical work operations.

d. Ability to deal effectively with individuals or groups representing widely divergent backgrounds, interests, and points of view.

(6) GS-13

(a) Experience. Completion of at least 1 year of experience equivalent to the next lower level, and must fully meet the KSAs at that level. In addition, the candidate must demonstrate the following professional KSAs and potential to acquire the assignment specific KSAs designated by an asterisk (*):

(b) Demonstrated Knowledge, Skills, and Abilities

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

*2. Knowledge of the most complex and specialized clinical technology including service, system administration, training, and quality assurance.

*3. Expert knowledge of, and the ability to interpret and apply, complex codes, regulations, guidelines, and standards associated with the biomedical engineering field.

(c) Assignment. At this level, employees may be in non-supervisory, supervisory, or research positions. For all assignments above the full performance level, the higher-level duties must consist of significant scope, complexity (difficulty), and range of variety, and be performed by the incumbent at least 25% of the time.

1. Biomedical Engineer (Clinical): Supports and advances patient care by applying engineering and managerial skills to healthcare technology as demonstrated by at least 4 of the following major responsibilities:

a. Responsibility for an equipment management program that meets current JCAHO and NFPA requirements. The breadth of technology is typical of a tertiary care and/or university-affiliated institution.
b. Assures provision of a continuing education program for clinical staff addressing the principles and application of medical instrumentation used in the delivery of health care. This includes a curriculum that addresses the safe and effective use of medical equipment and/or technology.

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

d. 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.

e. Conducts capital asset and infrastructure planning for medical equipment spanning initial concept, installation, and effective implementation of complex medical equipment.

f. Serves as institutional expert who directly supports the most complex and specialized clinical technology including service, system administration, training, and quality assurance.

2. Supervisory Biomedical Engineer (Clinical). The supervisory biomedical engineer (clinical) is responsible for the professional and administrative management of a biomedical engineering section in a tertiary care and/or university-affiliated facility. Such individuals typically 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 medical equipment inventory is available for patient care activities. In addition to the core competencies for GS-13 level positions, the supervisory biomedical engineer (clinical) must demonstrate the following professional KSAs and potential to acquire the assignment specific KSAs designated by an asterisk (*):

a. Ability to initiate new ideas and approaches, and demonstrate resourcefulness.

b. Ability to manage resources, i.e., space, equipment, supplies, staff, at the local level.

c. Ability to draft and/or recommend local policies and/or directives.

d. Skill in managing a biomedical engineering program at the local level.

3. Biomedical Engineer (Research). 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; and disseminating research findings at the local facility, and interacting with clinicians and clinical biomedical engineers. In addition to the core competencies for the GS-13 level, the biomedical engineer (research) must demonstrate the following professional KSAs and potential to acquire the assignment specific KSAs designated by an asterisk (*):
a. Knowledge of, and ability to apply, appropriate scientific methods in the design and execution of basic and applied research in the field of biomedical engineering.

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

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

(7) GS-14

(a) **Experience.** Completion of at least 1 year of experience equivalent to the next lower level, and must fully meet the KSAs at that level. In addition, the candidate must demonstrate the following professional KSAs and demonstrate the potential to acquire the assignment specific KSAs designated by an asterisk (*):

(b) **Demonstrated Knowledge, Skills, and Abilities**

1. Advanced knowledge of, and ability to interpret and apply, relevant codes, regulations, guidelines, and standards associated with biomedical engineering to support the needs of 1 or more facility.

2. Ability to effectively communicate both orally and in writing with a wide variety of individuals, including technical and professional clinical staff, to convey highly technical information.

3. Ability to manage a recall and safety alert program for medical devices, medical device incident investigations to assure compliance with patient safety goals, SMDA, and JCAHCO requirements.

4. Advanced knowledge of, and ability to apply, the 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.

5. Ability to directly support the most complex and specialized clinical technology including service, system administration, training, and quality assurance.

(c) **Assignment.** At this level, employees may be in non-supervisory, supervisory, or research positions. For all assignments above the full performance level, the higher-level duties must consist of significant scope, complexity (difficulty), and range of variety, and be performed by the incumbent at least 25% of the time.

1. **Biomedical Engineer (Clinical).** Supports and advances patient care by applying engineering and managerial skills to healthcare technology as demonstrated by at least 4 of the following major responsibilities:

   a. Conducts an equipment management program that meets current JCAHCO and NFPA requirements. The breadth of technology is typical of a tertiary care and/or university-affiliated institution. Evaluates other programs in the Veterans Integrated Service Network (VISN), or for the national program office.
b. 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. Provides continuing education beyond the facility including the VISN and/or the national program office, or teaches at a higher learning institution.

c. Manages a recall and safety alert program for medical devices, including medical device incident investigations to assure compliance with patient safety goals, SMDA, and JCAHO requirements. Analyzes recall and safety alert programs for other medical centers and/or conducts medical equipment investigations for the VISN or national program office.

d. Serves as advisor to senior clinical and leadership staff on medical technology, including existing and emerging technology, addressing viability, long-term suitability, compatibility, and/or safety. Serves as technology advisor to assist VISN with technology management and assessment.

e. Conducts capital asset and infrastructure planning for medical equipment spanning initial concept, installation, and effective implementation of complex medical equipment. Participates at the VISN and/or national level with capital asset planning. Analyzes organizational and operational problems and develops timely and economical solutions to meet facility, VISN, and/or national needs.

f. Serves as institutional expert who directly supports the most complex and specialized clinical technology including service, system administration, training, and quality assurance for multiple sites.

2. Supervisory Biomedical Engineer (Clinical). The supervisory biomedical engineer (clinical) is responsible for the professional and administrative management of a biomedical engineering section in a facility with complexity equal to a tertiary care and/or university-affiliated facility. Such individuals typically have responsibility for supervising technical staff including engineers, biomedical engineering technicians, and other technical staff. 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 financial management of budget resources allocated to support quality assurance and maintenance activities necessary to assure the facility medical equipment inventory is available for patient care activities.

At this level the supervisory biomedical engineer (clinical), is assigned oversight responsibility to establish operating policy for other professional engineers at the facility and/or other professional engineers in the VISN. In addition to the core competencies for the GS-14 level, the supervisory biomedical engineer (clinical) must demonstrate the following professional KSAs and potential to acquire the assignment specific KSAs designated by an asterisk (*):

a. Skill in interpersonal relationships including conflict resolution.

*b. Ability to work collaboratively with other disciplines, upper management, VHA Central Office, and/or VISN level staff.

*c. Ability to implement national policies.
d. Ability to develop and recommend new or revised policies that are consistent with organizational goals and objectives.

3. Biomedical Engineer (Research). 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 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. In addition to the core competencies for the GS-14 level, the biomedical engineer (research) must demonstrate the following professional KSAs and potential to acquire the assignment specific KSAs designated by an asterisk (*):

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

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

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

(8) GS-15. The Under Secretary for Health, or designee, may approve the assignment of a biomedical engineer at the GS-15 level when the composite record of qualifications, scope, and complexity of the assignment justify such action.

(a) Experience. Completion of at least 1 year of experience equivalent to the next lower level, and must fully meet the KSAs at that level. In addition, the candidate must demonstrate the following professional KSAs and potential to acquire the assignment specific KSAs designated by an asterisk(*):

(b) Demonstrated Knowledge, Skills, and Abilities

1. Knowledge of, and 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.

2. Ability to effectively communicate, both orally and in writing, on technical information with a wide variety of individuals including senior VHA managers.

*3. Knowledge of, and ability to apply, the principles, theories, concepts, and practices of the biomedical engineering profession to establish a national recall and safety alert program, and/or conduct medical equipment investigations for the national program office.

(c) Assignment. At this level, employees may be in non-supervisory, supervisory, or research positions. For all assignments above the full performance level, the higher-level duties must consist of significant scope, complexity (difficulty), and range of variety, and be performed by the incumbent at least 25% of the time.
1. **Biomedical Engineer (Clinical).** The biomedical engineer (clinical) supports and advances patient care by applying engineering and managerial skills to healthcare technology as demonstrated by the following major responsibilities:

   a. Establishes national criteria for conduct of an equipment management program that meets current JCAHO and NFPA requirements; manages a national center for engineering programs that provides solutions to medical technology and biomedical engineering issues; or conducts a multi-medical center equipment management program and serves as a national expert in biomedical engineering and evaluates other programs in the VISN or for the national program office.

   b. 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 and national level for professional engineering, and other medical center staff as appropriate on engineering topics.

   c. Establishes a national recall and safety alert program for medical devices, including medical device incident investigations, consistent with patient safety goals and compliant with SMDA and JCAHO requirements; or analyzes recall and safety alert programs for multiple medical centers and conducts medical equipment investigations for the VISN as well as high profile medical equipment investigations for the national program office.

   d. Works with clinical programs at the national level to identify medical equipment needs and priorities, and determine maintenance and quality assurance requirements. Participates in technology assessment activities for the Under Secretary for Health; or serves as advisor to senior clinical and leadership staff on medical engineering technology (including existing and emerging technology) for multiple sites addressing viability, long-term suitability, compatibility, and/or safety. Participates in technology assessment to support national program office requirements.

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

2. **Biomedical Engineer (Research).** 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; and 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. In addition to the core competencies for the GS-15 level, the biomedical engineer (research) must demonstrate the following professional KSAs and potential to acquire the assignment specific KSAs designated by an asterisk (*):

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

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

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

4. 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.

Authority: 38 U.S.C. §§ 7402, 7403.}