STATEMENT OF WORK

Radiation Support and Related Services

SCOPE OF CONTRACT

The Radiation Oncology Branch (ROB), Center for Cancer Research (CCR), National Cancer Institute (NCI), National Institute of Health (NIH), Bethesda, Maryland is responsible for providing radiation therapy treatments and related services to clinical protocol patients at the Clinical Center, NIH. These treatments will take place on-site, using linear accelerators, simulators, and dosimetry equipment.

The Contractor shall:

1) provide radiation therapy treatments, dosimetry treatment plans and verification, physics services, and related services as required by the Statement of Work; 2) operate associated equipment in the ROB such as high energy linear accelerators, radiation therapy simulators, CT scanners, radiation therapy treatment planning computers, associated dosimetry equipment, medical laboratory equipment, and MRI equipment; 3) provide on-call emergency radiation services, when required, in accordance with established radiation therapy practices, and 4) participate in on-site training. All staff shall have the appropriate board or registry certifications and appropriate state licensure for the field of practice as evidence by the curriculum vitae (CV).

TECHNICAL REQUIREMENTS

Independently and not as an agent of the Government, the Contractor shall be required to furnish all the necessary services, qualified personnel, materials, equipment, and facilities, not otherwise provided by the Government, as needed to perform the work for the Radiation Oncology Branch as identified herein.

Initial Transition Plan

Upon contract award, the draft initial transition plan submitted with the initial technical proposal will be revised, if necessary, and the draft initial transition plan will become the final initial transition plan upon approval of the Contracting Officer's Representative (COR). The final initial transition plan shall be followed to ensure an orderly, efficient, and expedient transition of all contract activities as soon as possible, but not later than 15 days after contract award. Problems or concerns anticipated or encountered shall be immediately communicated to the COR and an approved resolution pursued.

Quality Control Plan

Within 15 calendar days of contract award, the draft Quality Control Plan submitted with the initial technical proposal shall be submitted to the COR for review and approval. The plan shall include:

1. The methodology that will be used to monitor performance of the on-site work.

2. A system for periodic inspection and timely identification and correction of deficiencies.

Radiation Therapy Treatments

The Contractor shall provide radiation therapy treatments, dosimetric calculations, and measurements based on HIPAA Medical Code Sets identified by the Healthcare Common Procedure Coding System (HCPCS) Current Procedural Terminology (CPT) procedure codes. Codes used at the National Cancer Institute (NCI) include, but are not limited to, the following:

1. 77413 – Radiation treatment delivery, three or more separate treatment areas, blocking, transgential ports, wedges, rotational beam, compensators, special particle beam, 6-10 MeV.

2. 77414 – Radiation treatment delivery, three or more separate treatment areas, blocking, transgential ports, wedges, rotational beam, compensators, special particle beam, 11-19 MeV.

3. 77408 – Radiation treatment delivery, single treatment area, single port or parallel opposed ports, simple blocks or no blocks, 6-10 MeV.

4. 77409 – Radiation treatment delivery, single treatment area, single port or parallel opposed ports, simple blocks or no blocks, 11-19 MeV.

5. 77403 – Radiation treatment delivery, single treatment area, single port or parallel opposed ports, simple blocks or no blocks, 6-10 MeV.

6. 77404 – Radiation treatment delivery, single treatment area, single port or parallel opposed ports, simple blocks or no blocks, 11-19 MeV.

7. 77372 – Radiation treatment delivery, stereotactic radiosurgery (SRS), complete course of treatment of cranial lesion(s) consisting of 1 session, linear accelerator based.

8. 77373 – Stereotactic body radiation therapy, treatment delivery, per fraction to 1 or more lesions, including image guidance, entire course not to exceed 5 fractions.

9. 77418 – Intensity modulated treatment delivery, single or multiple fields/arcs, via narrow spatially and temporally modulated beams, binary, dynamic MLC, per treatment session.

10. 77290 – Therapeutic radiology simulation-aided field setting; complex.

11. 77295 – Therapeutic radiology simulation-aided field setting; 3-dimensional.

12. 77334 – Treatment devices, design and construction; complex (irregular blocks, special shields, compensators, wedges, molds or casts).

Dosimetry Treatment Plans and Verification

The Contractor shall provide dosimetry treatment plans, and plan verifications, as requested by attending physicians, based upon the American Medical Billing Codes. Codes used at the National Cancer Institute (NCI) include, but are not limited to, the following:

1. 77310 – Teletherapy, isodose plan (whether hand or computer calculated), intermediate (three or more treatment ports directed to a single area of interest).

2. 77315 – Same as above, complex (mantle or inverted Y, tangential ports, the use of wedge, compensators, complex blocking, rotational beam, or special beam considerations).

3. 77301 – Intensity modulated radiotherapy plan, including dose-volume histograms for target and critical structure partial tolerance specifications.

4. 77321 – Special teletherapy port plan, particles, hemibody, total body.

5. 77328 – Complex (multiplane isodose plan, volume implant calculations, over 10 sources/ribbons used, special spatial reconstruction, remote after loading brachytherapy, over 12 sources).

Physics Services

The Contractor shall provide physics services, including commissioning of radiotherapy equipment; periodic quality assurance measurements of equipment; quality assurance and verification of treatment plans; quality assurance of patient records, including paper and electronic charts; based upon the American Medical Billing Codes. Codes used at the National Cancer Institute (NCI) include, but are not limited to, the following:

1. 77336 – Continuing medical physics consultation, including assessment of treatment parameters, quality assurance of dose delivery, and review of patient treatment documentation in support of the radiation oncologist, reported per week of therapy.

2. 77330 – Special medical radiation physics consultation.

3. 77399 – Unlisted procedure, medical radiation physics, dosimetry and treatment devices, and special services.

4. 77331 – Special dosimetry (e.g. TLD, microdosimetry) only when prescribed by the treating physician.

Personnel Requirements

The Contractor shall:

1. Ensure that the proposed Chief Radiation Therapist is certified by the American Association of Radiation Technologists (ASRT) in Radiation Technology, possesses an Associate of Science degree in Radiation Science, and has at least two years of supervisory experience as Chief or Assistant Chief Therapist.

2. Ensure that the proposed Radiation Therapists are certified by the ASRT in Radiation Technology, possess an Associate of Science degree, and have at least one year of experience as a Radiation Therapist.

3. Provide documentation that verifies that the Radiation Therapists have experience in operating **all** of

the following equipment, including: Varian RapidArc accelerator, Tomotherapy Hi-ART helical tomotherapy unit, Nucletron MicroSelectron High-Dose-Rate Remote Afterloader, Varian ARIA patient management system, and Philips Brilliance CT Simulator. Copies of certifications shall be supplied.

4. Ensure the Supervisory Physicist is certified by the American Board of Radiology or an equivalent organization in Therapeutic Radiological Physics, Radiation Therapy Physics or Radiological Physics, possess a Master of Science degree in Physics, Biology, Nuclear Engineering or Medical Physics, and has at least five years of experience.

5. Ensure the Supervisory Physicist has at least one year of experience in the treatment planning of proton radiotherapy.

6. Ensure the Supervisory Physicist has been a Nuclear Regulatory Commission-recognized Authorized Medical Physicist for at least three years and has supervisory experience for at least three years.

7. Ensure the Supervisory Physicist has experience in assisting with all physics and dosimetry aspects of clinical research as demonstrated by authorship in oral and poster presentations at scientific meetings and authorship of articles published in peer-reviewed journals.

8. Ensure the Supervisory Physicist has factory-based training in Tomotherapy Hi-ART planning, quality assurance, operation, and first-line maintenance; Radionics XKnife planning, operation, and maintenance; Varian RapidArc planning, On-Board Imaging, and basic accelerator maintenance; and Nucletron Oncentra-BPS brachytherapy planning, and quality assurance and MicroSelectron operation.

9. Ensure the Staff Physicists have a minimum of a Master's Degree in Physics, Medical Physics, or a related discipline and five years of experience; or a Doctoral degree with three years of experience.

10. Ensure the Staff Physicists are certified by the American Board of Radiology in Therapeutic Radiologic Physics, Radiation Therapy Physics or Radiologic Physics.

11. Ensure the Staff Physicists have factory-based specialty physics training on at least one of the following systems: Varian RapidArc, Nucletron MicroSelectron, and Oncentra BPS, Tomotherapy or XKnife radiosurgery, and have had on-site training on the remainder of the systems.

12. Ensure Junior Physicists have a minimum of a Master's Degree in Physics, Medical Physics, or a related discipline and two years of experience.

13. Ensure Junior Physicists are graduates of a CAMPEP-approved medical physics residency program and shall be eligible for the ABR accreditation process. They shall complete all requirements for board certification within five years from the date of hire. Junior Physicists shall matriculate to Staff Physicists upon successful completion of the ABR certification process, and upon approval of the Government.

14. Ensure Dosimetrists are certified by the Medical Dosimetry Certification Board of the American Association of Medical Dosimetrists (AAMD), possess an Associate of Science degree in Radiation Science, and have at least five years of experience.

15. Ensure Dosimetrists have factory-based training on the Tomotherapy Hi-ART treatment planning system and the Radionics XKnife radiosurgery planning system.

16. Ensure Imaging Scientists have a Ph.D. in imaging science or computer science specializing in image processing, and have a minimum of 2 years of experience, plus a demonstrated competency through publications in recognized scientific journals or patents.

17. Ensure Biomedical Engineers have a Bachelor of Science and minimum of 2 years of experience specializing in radiation oncology.

General Technical Requirements

The Contractor shall:

1. Ensure that physics and dosimetry personnel consist of a Supervisory Physicist, Staff Physicists, a possible Junior Physicist, and 1-2 Dosimetrists. There may or may not be a Junior Physicist, but there shall be no more than one. There shall be at least one Dosimetrist.

2. Ensure that only the contractor Supervisory Physicist reports to and takes direction from the Contracting Officer's Representative (Chief of Radiation Physics).

3. All Radiation Therapists shall have experience treating patients according to specifications set forth in clinical research protocols and shall be familiar with the treatment and delivery aspects of those protocols.

4. Provide approximately 3,500 treatments for the base period and subsequent option periods for a possible total of 24,500 over seven (7) years, of all treatment procedures (fractions) over the duration of this contract.

5. Perform treatment procedures at the National Institutes of Health Clinical Center located in Bethesda, Maryland, or at any additional location as specified by the Government. The NCI shall furnish the Government equipment and supplies to perform the Statement of Work.

6. Perform treatment procedures as required five (5) days per week, fifty-two (52) weeks per year, except Federal holidays. Core business hours at the NCI are 8:00 AM to 4:30 PM, Monday through Friday. Occasionally, the Contractor may be required to adjust its work schedule to perform treatment procedures to accomplish project needs. Additional hours may be required on an as needed basis due to emergency or scheduling requirements.

7. Perform all work in accordance with applicable laws and regulations pertaining to the work.

8. Devote a minimum of 10% time educating radiation oncology residents, medical physics residents, postdoctoral associates, summer students or other personnel as deemed appropriate by the Contracting Officer's Representative.

9. Keep all medical certifications current.

10. Ensure that no Contractor personnel be exposed to occupational radiation greater than the standard allowed by Local, State, or Federal Laws or Regulations. The Contractor shall certify that all work

performed meets or exceeds the safety requirements of Federal radiation standards for occupational exposure.

11. Participate in on-site training as required by the COR and NIH community, including, but not limited to annual radiation safety training and annual security awareness training.

12. Inform the NCI Contracting Officer Representative (COR) of any unforeseen circumstances that may delay timely completion or progress of study activities. All study-related activities, documents, and procedures must be approved by the COR prior to implementation. Types of support to be provided by the Contractor in the support of studies may vary.

Final Transition for all Contract Activities

Within the first 180 days after contract award, the Contractor shall develop and submit a draft final transition plan which will describe the Contractor's strategy for transferring work from this contract to a successor contract, in the event a final transition would be required. The plan must include plans for transfer of policies and procedures; transition of equipment; and transfer of relevant files and records. The draft final transition plan will be revised, if necessary, and the draft final transition plan will become the final transition plan upon approval of the COR. The approved final transition plan shall be followed to ensure an orderly, efficient, and expedient transition of all contract activities by the contract completion date.

OPTIONS for Increased Quantity of Personnel

Over the life of the Contract, the Government may require additional personnel. The Contractor shall propose optional staffing, to be located in the Radiation Oncology Branch, NIH, as follows:

Option A: Radiation Oncologist (Physician) – Full Time
The Contractor shall provide staff certified in Radiation Oncology by the American Board of Radiology, or an equivalent organization, to function in collaboration with the Clinical Center staff of the Radiation Oncology Branch. The Contractor shall:

1. Provide a Radiation Oncologist.

2. Ensure the Radiation Oncologist holds a license to practice medicine in the state of Maryland.

3. Utilize the Clinical Research Information System (CRIS) and other clinical databases as needed for clinical care, documentation and data collection.

4. Collaborate with multidisciplinary team members relating to standard patient care.

5. Communicate patient management needs and research needs to members of the patient care team, and inform attending physicians as to changes in the patients' conditions and medical treatment plans.

6. Communicate with referring physicians, other health care professionals and patients regarding the diagnosis and treatment of the diseases under study, as well as eligibility for types of care, and refer those questions that cannot be answered personally to primary investigators, attending and clinic physicians.

7. Interpret routine laboratory results and explain their significance to both patients and referring physicians.

8. Maintain contact with patients and referring physicians to explain patients' conditions and symptoms and to assure that specific guidelines regarding each patient are followed and that the radiation therapists is performing services correctly as mandated by the patients physician.

9. Provide follow-up on patients throughout a study to schedule tests and follow-up examinations.

10. Perform history and physical examinations and identify normal and abnormal findings on history examination and commonly performed laboratory studies.

11. Record pertinent patient data.

12. Assess patients to determine the need for medical attention. Order and perform appropriate laboratory and diagnostic studies.

13. Order medications.

14. Request consultations from appropriate medical and surgical specialties.

15. Discuss symptoms of the diseases and possible therapies with other medical staff.

16. Contact the physician if the patient appears acutely ill.

17. Develop, document and implement a patient management plan in response to the data obtained.

18. Counsel patients, and provide education to patient and family members.

19. Serve as a patient advocate.

Option B: Nurse Practitioner – Full Time

The Contractor shall provide a Nurse Practitioner to function as a certified physician assistant in collaboration with the senior staff of the Radiation Oncology Branch. The Contractor shall practice in an expanded role, participating as a member of the multidisciplinary team providing comprehensive care to patients. The Contractor shall:

1. Provide a Nurse Practitioner.

2. Ensure the Nurse Practitioner holds a license to practice medicine in the state of Maryland. Nurse Practitioner must have a minimum of a Master Degree in Nursing or related field and have a certification as an Advanced Oncology Certified Nurse Practitioner (AOCNP) by the Oncology Nursing Certification Corporation (ONCP) or equivalent organization.

3. Provide health care maintenance diagnostic and therapeutic services, education and counseling within the special boundaries of his/her specialty area of education and clinical preparation.

4. Function independently as a nurse practitioner for a selected patient population under the general supervision of a medical staff fellow.

5. Expand and extend the scope of nursing practice through the provision coordination and facilitation of clinical care and participating in medical and nursing research.

6. Secure health development and family history; assess the patients physical status through the performance of a physical examination; perform or request screening and diagnostic tests; disseminate between normal and abnormal findings and education; and evaluate, modify, and revise care plans at appropriate intervals in collaboration with other members of the health care team.
7. Recognize major and minor variations in health status and collaborate with the physician for the management of the patients medical care requirements. Prescribe appropriate therapies within limits approved by the medical board, Clinical Center.

8. Maintain complete and current patient record which includes history, physical examination problem identification, and plan of care, intervention made, and evaluation of response.

9. Serve as a patient advocate.

Option C: Physician Assistant – Full Time

The Contractor shall provide a Physician Assistant to function as a certified physician assistant in collaboration with the senior staff of the Radiation Oncology Branch. The Contractor shall practice in an expanded role, participating as a member of the multidisciplinary team providing comprehensive care to patients. The Contractor shall:

1. Provide a Physician Assistant.

2. Ensure the Physician Assistant holds a license to practice medicine in the state of Maryland. Physician Assistant must have a minimum of a master's degree in either Physician Assistant Studies (MPAS), Health Science (MHS), or Medical Science (MMSc) and must be certified by the National Commission on Certification of Physician Assistants (NCCPA) by passing the Physician Assistant National Certifying Exam (PANCE).

3. Act as a liaison between the NIH care team and patients' primary health care providers.

4. Provide direct patient care responsibilities for outpatients, as well as inpatients, and independently assess acute and non-acute clinical problems and toxicities.

5. Perform history and physical examinations and identify normal and abnormal findings on history examination and commonly performed laboratory studies.

6. Record pertinent patient data.

7. Assess patients to determine the need for medical attention. Order and perform appropriate laboratory and diagnostic studies.

8. Order medications.

9. Request consultations from appropriate medical and surgical specialties.

10. Discuss symptoms of the diseases and possible therapies with other medical staff.

11. Analyze trends in patient conditions.

12. Develop, document and implement a patient management plan in response to the data obtained.

13. Counsel patients, and provide education to patient and family members.

14. Serve as a patient advocate.

Monthly Statistical Treatment Report (Exhibit #1)

		Therapy	Patient	Treatment Site																
	Tx	Fld	New	Rs	Ped	Br Primary	Cord	H&D	Lung	Breast	GI	GU	GYN	Lym/ Leuk	Bone	Ped	Unknown	Benign	Mets	Others
Treatment																				
Simulation																				
Total																				
Year to date 2008																				
Jan																				
Feb																				
Mar																				
Apr																				
May																				
June																				
July																				
Aug																				
Sept																				
Oct																				
Nov																				
Dec																				
Total																				

Quarterly Treatment Report (Exhibit #2)

		Therapy	Patient	Treatment Site																
	Tx	Fld	New	Rs	Ped	Br Primary	Cord	H&D	Lung	Breast	GI	GU	GYN	Lym/ Leuk	Bone	Ped	Unknown	Benign	Mets	Others
Treatment																				
Simulation																				
Total																				
First Quarter																				
Jan																				
Feb																				
Mar																				
Total																				
Second Quarter																				
April																				
May																				
June																				
Total																				
Third Quarter																				
July																				
Aug																				
Sept																				
Total																				
Fourth Quarter																				
Oct																				
Nov																				
Dec																				
Total																				