American Osteopathic Board of Radiology

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October 19, 2005

U.S. Nuclear Regulatory Commission ATTN: Mr. Thomas H. Essig, Chief Materials Safety and Inspection Branch (MS T8F3) 11545 Rockville Pike Rockville, MD 20852

Dear Mr. Essig

I am writing in response to your letter of September 9, 2005, in which the American Osteopathic Board of Radiology (AOBR) was seeking recognition of its certification processes by the U.S. Nuclear Regulatory Commission (NRC). Thank you for your review and subsequent comments. We are presenting revisions to our original request dated July 26, 2005, below.

ISSUES 1 AND 2

List of Requested Specialties (Revised 9-22-2005)

Subpart D--Unsealed Byproduct Material--Written Directive Not Required

- § 35.190 Training for uptake, dilution, and excretion studies. (Diag Rad & Rad)
- § 35.290 Training for imaging and localization studies. (Diag Rad & Rad)

Subpart E--Unsealed Byproduct Material--Written Directive Required

- § 35.390 Training for use of unsealed byproduct material for which a written directive is required. (Diag Rad & Rad)
- § 35.392 Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries). (Diag Rad & Rad)
- § 35.394 Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries). (Diag Rad & Rad)

Subpart F--Manual Brachytherapy

§ 35.490 Training for use of manual brachytherapy sources. (Rad, RO, & Therapeutic Rad) Subpart G--Sealed Sources for Diagnosis

§ 35.590 Training for use of sealed sources for diagnosis. (Rad, Diag Rad, RO, & Therapeutic Rad)

Subpart H--Photon Remitting Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units

§ 35.690 Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units. (Rad, RO, & Therapeutic Rad)

ISSUE 3

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<u>Candidates seeking certification for the following medical uses must meet the specific training and experience requirements as stated below:</u>

10 CFR 35.190 (a)(1) Training for update, dilution and excretion studies

- 1. Complete 60 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed byproduct material for uptake, dilution, and excretion studies that includes the topics listed below:
 - a. Complete sixty (60) hours of classroom and laboratory training in the following areas:
 - i. Radiation physics and instrumentation
 - ii. Radiation protection
 - iii. Mathematics pertaining to the use and measurement of radioactivity
 - iv. Chemistry of byproduct material for medical use; and
 - v. Radiation biology
 - b. Work experience, under the supervision of an authorized user who meets the requirements in 35.190, 35,290, 35.390, or before October 24, 2005 35.910, 35.920, or 35.930 or equivalent Agreement State requirements, involving
 - i. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys
 - ii. Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters
 - iii. Calculating, measuring, and safely preparing patient or human research subject dosages
 - iv. Using administrative controls to prevent a medical event involving the use of unsealed byproduct material
 - v. Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and
 - vi. Administering dosages of radioactive drugs to patients or human research subjects

35.290 (a)(1) Training for imaging and localization studies

- 1. Complete 700 hours of training and experience, including a minimum of 80 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for imaging and localization studies. The training and experience must include, at a minimum:
 - a. Classroom and laboratory training in the following areas:
 - i. Radiation physics and instrumentation
 - ii. Radiation protection
 - iii. Mathematics pertaining to the use and measurement of radioactivity
 - iv. Chemistry of byproduct material for medical use
 - v. Radiation biology
 - b. Work experience, under the supervision of an authorized user, who meets the requirements in 35.290, or 35.290(c)(1)(ii)(G) and 35.390, or before October 24, 2005, 35.920, or equivalent Agreement State requirements, involving
 - i. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys
 - ii. Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters

- iii. Calculating, measuring and safely preparing patient or human research subject dosages
- iv. Using administrative controls to prevent a medical event involving the use of unsealed byproduct material
- v. Using procedures to safely contain spilled radioactive material and using proper decontamination procedures
- vi. Administering dosages of radioactive drugs to patients or human research subjects; and
- vii. Eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs

<u>35.390 (a)(1)</u> Training for use of unsealed byproduct material for which a written directive is required

- 1. Complete 700 hours of training and experience, including a minimum of 200 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material requiring a written directive. The training and experience must include
 - a. Classroom and laboratory training in the following areas:
 - i. Radiation physics and instrumentation
 - ii. Radiation protection
 - iii. Mathematics pertaining to the use and measurement of radioactivity
 - iv. Chemistry of byproduct material for medical use
 - v. Radiation biology
 - b. Work experience, under the supervision of an authorized user, who meets the requirements in 35.390, or before October 24, 2005, 35.930, or equivalent Agreement State requirements. A supervising authorized user, who meets the requirements in 35.390(b) or, before October 24, 2005, 35.930(b), must also have experience in administering dosages in the same dosage category or categories (i.e., 35.390(b)(1)(ii)(G) as the individual requesting authorized user status. The work experience must involve
 - i. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys
 - ii. Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters
 - iii. Calculating, measuring and safely preparing patient or human research subject dosages
 - iv. Using administrative controls to prevent a medical event involving the use of unsealed byproduct material
 - v. Using procedures to safely contain spilled byproduct material safely and using proper decontamination procedures
 - vi. Administering dosages of radioactive drugs to patients or human research subjects involving a minimum of three cases in each of the following categories for which the individual is requesting authorized user status –
 - a) Oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131 for which a written directive is required
 - b) Oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131
 - c) Parenteral administration of any beta emitter or a photon-emitting radionuclide with a photon energy less than 150 keV for which a written directive is required

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d) Parenteral administration of any other radionuclide, for which a written directive is required

<u>35.490(a)(1)</u> Training for the use of manual brachytherapy sources

- 1. Complete a structured educational program in basic radionuclide handling techniques applicable to the use of manual brachytherapy sources that includes:
 - a. 200 hours of classroom and laboratory training in the following areas:
 - i. Radiation physics and instrumentation
 - ii. Radiation protection
 - iii. Mathematics pertaining to the use and measurement of radioactivity
 - iv. Radiation biology
 - b. 500 hours of work experience, under the supervision of an authorized user who meets the requirements in 35.490, or, before October 24, 2005 35.940, or equivalent Agreement State requirements at a medical institution, involving:
 - i. Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys
 - ii. Checking survey meters for proper operation
 - iii. Preparing, implanting, and removing brachytherapy sources
 - iv. Maintaining running inventories of material on hand
 - v. Using administrative controls to prevent a medical event involving the use of byproduct material
 - vi. Using emergency procedures to control byproduct material
- 2. Complete 3 years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirement in 35.490, or before October 24, 2005, 35.940, or equivalent Agreement State requirements, as part of a formal training program approved by Program and Trainee Review Committee of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required in paragraph 1 (b) above.

35.590(b) and (c) Training for use of sealed sources for diagnosis

- 1. Complete 8 hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device. The training must include
 - a. Radiation physics and instrumentation
 - b. Radiation protection
 - c. Mathematics pertaining to the use and measurement of radioactivity
 - d. Radiation biology
- 2. Complete training in the use of the device for the uses requested

35.690(a)(1) Training for use of remote afterloader units

- 1. Complete a structured educational program in basic radionuclide techniques applicable to the use of a sealed source in a therapeutic medical unit that includes
 - a. 200 hours of classroom and laboratory training in the following areas
 - i. Radiation physics and instrumentation
 - ii. Radiation protection
 - iii. Mathematics pertaining to the use and measurement of radioactivity
 - iv. Radiation biology
 - b. 500 hours of work experience, under the supervision of an authorized user who meets the requirements in 35.690, or, before October 24, 2005 35.960, or equivalent Agreement State requirements at a medical institution, involving
 - i. Reviewing full calibration measurements and periodic spot-checks
 - ii. Preparing treatment plans and calculating treatment doses and times
 - iii. Using administrative controls to prevent a medical event involving the use of byproduct material

- iv. Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console
- v. Checking and using survey meters
- vi. Selecting the proper dose and how it is to be administered
- Complete 3 years of supervised clinical experience in radiation therapy, under an authorized user who meets the requirements in 35.690, or, before October 24, 2005, 35.960, or equivalent Agreement State requirements, as part of a formal training program approved by the Program and Trainee Review Committee of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by paragraph 1(b) above.

ISSUE 4

In accordance with 10 CFR 35.190(a)(2) and 35.290(a)(2), the following examination areas of the Diagnostic Radiology certification examination listed under "Physics of Medical Imaging, Biological Effects and Safety" assess knowledge and competence in "radionuclide handling and quality control."

- Radiological Physics (radiation production and interaction with matter)
- Radiation Biology (health effects)
- Radiation Safety and Protection
- Nuclear Medicine

ISSUE 5

In accordance with 10 CFR 35.390(a)(2), the following examination areas of the **Diagnostic Radiology** certification examination listed under "Physics of Medical Imaging, Biological Effects and Safety" assess knowledge and competence in "radiation safety, radionuclide handling, quality assurance, and clinical use of unsealed byproduct material for which a written directive is required."

- Radiological Physics (radiation production and interaction with matter)
- Radiation Biology (health effects)
- Radiation Safety and Protection
- Nuclear Medicine

In accordance with 10 CFR 35.390(a)(2), the following examination areas of the **Radiation Oncology** certification examination assess knowledge and competence in "radiation safety, radionuclide handling, quality assurance, and clinical use of unsealed byproduct material for which a written directive is required."

- Radiobiology
- Physics
- Radiation Safety and Protection
- Lung
- Head and Neck
- CNS Malignancies
- Gastrointestinal Malignancies
- Genitourinary Malignancies
- Gynecologic Malignancies
- Breast
- Skin
- Sarcoma Malignancies
- Pediatrics
- Lymphoma/Leukemia Malignancies
- Nuclear Medicine
- Head and Neck

The oral examination in Radiation Oncology covers six sections as listed in our letter of July 26, 2005, page 4. The examination of these six sections include discussion on treatment planning and highlights various treatment management techniques which include brachytherapy, stereotactic radiosurgery, where

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appropriate, the administration of radionucleotides, radiation safety as it relates to the oral and IV administration of radionucleotides and general radiation safety principles. Multiple cases are presented and the candidates must discuss the entire management from diagnosis, therapeutic options, treatment planning and follow-up surveillance.

ISSUE 6

In accordance with 10 CFR 35.490(a)(2), the following examination areas of the Radiation Oncology certification examination assess knowledge and competence in "radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of manual brachytherapy."

- Radiation Biology
- Physics
- Radiation Safety and Protection
- Lung
- Head and Neck
- CNS Malignancies
- Gastrointestinal Malignancies
- Genitourinary Malignancies
- Gynecologic Malignancies
- Breast
- Skin
- Sarcoma Malignancies
- Pediatrics
- Lymphoma/Leukemia Malignancies
- Nuclear Medicine

The oral examination in Radiation Oncology covers six sections as listed in our letter of July 26, 2005, page 4. The examination of these six sections include discussion on treatment planning and highlights various treatment management techniques which include brachytherapy, stereotactic radiosurgery, where appropriate, the administration of radionucleotides, radiation safety as it relates to the oral and IV administration of radionucleotides and general radiation safety principles. Multiple cases are presented and the candidates must discuss the entire management from diagnosis, therapeutic options, treatment planning and follow-up surveillance.

ISSUE 7

In accordance with 10 CFR 35.690(a)(2), the following examination areas of the Radiation Oncology certification examination assess knowledge and competence in "radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of stereotactic radiosurgery, remote afterloaders and external beam therapy."

- Radiation Biology
- Physics
- Lung
- Head and Neck
- CNS Malignancies
- Gastrointestinal Malignancies
- Genitourinary Malignancies
- Gynecologic Malignancies
- Breast
- Skin
- Sarcoma Malignancies
- Pediatrics
- Lymphoma/Leukemia Malignancies
- Radiation Safety and Protection
- Nuclear Medicine

Mr. Thomas H. Essig, Chief

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The oral examination in Radiation Oncology covers six sections as listed in our letter of July 26, 2005, page 4. The examination of these six sections include discussion on treatment planning and highlights various treatment management techniques which include brachytherapy, stereotactic radiosurgery, where appropriate, the administration of radionucleotides, radiation safety as it relates to the oral and IV administration of radionucleotides and general radiation safety principles. Multiple cases are presented and the candidates must discuss the entire management from diagnosis, therapeutic options, treatment planning and follow-up surveillance.

The American Osteopathic Board of Radiology makes every effort to balance the questions in the different categories of the examination to test the candidates in the areas listed above and as listed in the NRC regulations.

ATTESTATION

The American Osteopathic Board of Radiology will require every candidate for certification in either Diagnostic Radiology or Radiation Oncology and his/her residency program director to submit an attestation form stating that the candidate has completed the requirements of training and experience as stated in NRC 10 CFR, Part 35, Subpart D-H. These forms will be a permanent part of the candidate's file.

Please do not hesitate to contact me if further information is required.

Sincerely

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Pamela A. Smith Executive Director

cc Kenneth P. Tarr, DO, Chair Mark S. Finkelstein DO, Vio

Mark S. Finkelstein, DO, Vice Chair Roy S. Teng, DO, Secretary-Treasurer Paul J. Chase, DO, Nuclear Medicine Section Chair Thomas M. Anderson, DO, Radiation Oncology Section Chair



BASIC STANDARDS FOR RESIDENCY TRAINING IN RADIATION ONCOLOGY

American Osteopathic Association

and the

American Osteopathic College of Radiology

Revised, BOT/1993 Revised, BOT 7/1994 Revised, BOT 2/1998 Revised, BOT 3/1999 Revised, BOT 2/2000 Revised, BOT 7/2001 Revised, BOT 2/2004 Revised, BOT 7/2004

Basic Standards for Residency Training in

Radiation Oncology

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BASIC STANDARDS FOR RESIDENCY TRAINING IN RADIATION ONCOLOGY

STANDARD I MISSION

The training of postdoctoral Osteopathic Physicians in the causes, prevention, evaluation and treatment of patients with cancer and other certain conditions which are amenable to the use of ionizing radiation. This entails providing education in the specialty of radiation oncology within an educational environment conducive to the development of a compassionate and competent osteopathic radiation oncologist.

STANDARD II

EDUCATIONAL PROGRAM GOALS AND OBJECTIVES

A. GOALS AND OBJECTIVES

The goals of a radiation oncology residency training program are to:

- 1. Provide learning experiences to promote a broad understanding of the role of radiation oncology and its relationship to other medical disciplines.
- 2. Develop measurable objectives to assess the progression of the resident during the fouryear training program.
- 3. Provide the radiation oncology resident with progressive responsibilities commencing with introductory training and progressing to independent professional practice of radiation oncology.
- 4. Provide the opportunity to develop the teaching skills of residents in radiation oncology
- 5. Provide the opportunity to develop interpersonal and communication skills and professional leadership and management skills.
- 6. Provide the opportunity to develop interest in and understanding of research in radiation oncology.
- 7. Prepare the resident to meet certification eligibility requirements of the AOA through the American Osteopathic Board of Radiology.
- 8. Develop the interest in lifelong learning in medical education and the understanding that lifelong learning and research are essential in radiation oncology.
- 9. Demonstrate a commitment to carrying out professional responsibility, adherence to ethical principles and sensitivity to a diverse patient population.
- 10. Demonstrate and apply knowledge of osteopathic principles and manipulative treatment (OMT) appropriate to the specialty of radiation oncology.

STANDARD III

INSTITUTIONAL REQUIREMENTS FOR PROGRAM APPROVAL

INSTITUTIONAL REQUIREMENTS

1. Be accredited by the American Osteopathic Association/Healthcare Facilities Accreditation Program (HFAP) or Joint Committee on Accreditation of Healthcare Organizations (JCAHO) and affiliated with an Osteopathic Postdoctoral Training Institution (OPTI) accredited by the American Osteopathic Association (AOA).

- 2. Document that the program meets the policies and procedures of the OPTI with which it is affiliated.
- 3. Meet all the requirements as formulated in the AOA <u>Basic Documents for Postdoctoral</u> <u>Training.</u>
- 4. The residency training program shall only commence after it has received the approval of the AOA's Executive Committee of the Council on Postdoctoral Training (ECCOPT)

Institutional facilities and resources must be adequate to provide educational opportunities to the resident. The institution is responsible for assuming the financial, technical and educational support for the program. The institution must provide the necessary space, facilities and learning environment for the establishment and maintenance of an AOA-approved program.

a. The institution shall have the following facilities:

5.

A medical library which is properly staffed and maintained by a qualified **i.** librarian. This library shall include access to current standard medical reference texts and medical journals or their electronic version, and computer-assisted literature search and internet capabilities, e.g. Medline. Maintain an adequate medical library containing carefully selected current texts (a list of recommended radiation oncology residency textbooks are available upon request from the AOCR office), medical journals and other appropriate publications covering the fields of radiation oncology, medical oncology, gynecologic oncology, pediatric oncology, central nervous oncology, and other oncologic sites and modalities, radiology, pathology as well as the various branches of general medicine and surgery. The library shall be in the charge of a qualified person who shall act as custodian of its contents and arrange for the proper cataloging and indexing that will facilitate investigative work by the residents. It is recommended that the radiation oncology library be housed within the department rather than in the general institution library. There must be a reference library for residents available on a 24 hour basis within the department.

- ii. Conference room(s) which are available for formal instruction.
- iii. Sleeping and lounge facilities and food facilities.
- iv. Faculty and administrative office space.
- v. Office space for residents.

6. The institution shall have a radiation safety program which includes:

- a. A designated radiation safety officer.
- b. Adequate monitoring and protection for all personnel and patients exposed to radiation.
- c. Standards for protection of personnel and patients that shall be in compliance with federal and state regulations.
- 7. The institution must have a full-time radiological physicist and full or part-time dosimetrist. The full-time radiological physicist must have time designated for resident teaching.
- 8. Must provide a written policy and procedure for the selection of residents. Admission to a residency program shall not be influenced by race, sex, religion, creed, national origin, age, sexual orientation, marital status, veteran status, disability or other legally protected

status. This policy applies to all phases of employment, including, but not limited to, recruitment, employment, placement, promotion, demotion, transfer, and administration of wage, salary, and benefits administration

- 9. Must retain resident logs and other resident records for a minimum of five years beyond the resident's completion of his/her program.
- Shall execute a contract with each resident in accordance with the AOA Basic 10. **Documents for Postdoctoral Training.**
- Upon satisfactory completion of the training program, the institution shall award the 11. resident an appropriate certificate of completion. The certificate shall confirm the fulfillment of the program requirements, starting and completion dates of the program and the name(s) of the training institution(s) and the program director(s). A copy of the certificate of completion or a letter of verification of completion must be submitted to the AOCR.
- The institution must adopt formal policies and the residents must be provided a current 12. edition of these policies. There must be a resident manual that will include, but is not limited to:
 - The rules and regulations stating the resident's duties and responsibilities. a. b. Leave policies.
 - Financial arrangements, including housing, meals, and other benefits, as may be c. determined by the institution and described in the resident contract.
 - d. Institutional policies and procedures for the supervision and evaluation of residents, due process (e.g., grievances, disciplinary action, academic deficiencies, or failure) and appeal processes.
 - Policies governing outside activities of a professional nature. e.

Institutional policies regarding contract renewal, contract interruption or f. cancellation, and the number of radiation oncology residency positions offered each year of training.

Institutional duty hours policies. g:

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- 13. To fulfill requirements of the basic standards or enhance training, the program director may arrange for required rotations with affiliated training sites, especially as related to gynecological oncology, pediatric oncology, central nervous system oncology and brachytherapy.
 - 'a. A program seeking to fulfill its requirements through affiliations with other AOA or ACGME accredited institutions must formulate formal affiliation agreements with these training sites. Affiliation agreements shall be signed by representatives of both the base institution and the affiliated training sites and - 1 a. a. M.M. maintained on file with the DME at the base institution.
 - Affiliation agreements must reflect desired educational goals and objectives of b. the rotation.

c. Residents on rotation at affiliated training sites shall remain under contract to the base institution. 4411446

Resident training logs shall reflect training and service to the affiliate site and shall be included in the resident records at the base institution. at kung song d

Written evaluation of the resident's performance at the affiliated site must be e. submitted by the on-site faculty to the Program Director at the base institution.

- 14. There must be effective, anonymous assessment of the radiation oncology residency program by the resident to the institution at least annually.
- 15. The institution shall develop and maintain ongoing, multi-modality conferences related to general tumor diagnosis and management, as well as site specific conferences such as breast cancer, lung cancer, colorectal cancer, etc. These conferences require attending staff participation.

B. DEPARTMENT OF RADIATION ONCOLOGY REQUIREMENTS

To be considered for approval of a residency program in radiation oncology, the department must:

- Provide sufficient patient volume and variety to properly train a minimum of three (3) residents in radiation oncology. The minimum staff/resident ratio is 1:2. The number of residents cannot exceed the number of radiation oncologists by greater than one. Patient caseload should be of sufficient magnitude to provide a broad experience in consultation, actual treatment, and follow-up of the various types of cancer and benign disease amenable to radiation therapy. To assure adequate numbers and variety of patients for residency training, it is recommended that the institution treat approximately 600 patients yearly and that the number of patients irradiated by the resident, under supervision, each year be no fewer than 125.
- 2. Have an adequate record system for all cases in which consultation, therapy, and followup care have been provided and a satisfactory pathologic cross file index using standard disease nomenclature. Provide adequate space and an atmosphere conducive to resident study and conferences.
- 3. Have radiation oncology equipment of modern design and shall meet the requirements and standards of federal, state and local regulations, shall be consistent with the workload of the institution. Training must include use of linear accelerators with electron capability as well as current treatment planning and computerized dosimetry equipment. The radiation therapy planning system should include three-dimensional conformal computerized treatment planning, a system for the construction of treatment aids, and equipment to perform interstitial and intracavitary brachytherapy also to include access to a CT simulator. Exposure to PET imaging correlation is required.
- 4. All radiologic technologists shall be appropriately trained and licensed where required

C. CONSORTIUM REQUIREMENTS

1.

Institutions seeking participation in a radiation oncology residency consortium must meet the following criteria:

- 1. Have a minimum of two (2) institutions participating that meet the following criteria:
 - a. A minimum of one (1) institution must meet the teaching faculty qualification as stated in Standard III, C, 1.
 - b. A member of the teaching faculty of each participating institution must be designated to assume responsibility for the day-to-day activities of the Program at that institution, with overall coordination by the Program Director.

Basic Standards for Residency Training in Radiation Oncology

- Ċ. . All participating institutions must be within a reasonable driving distance to make resident attendance at rounds and conferences practical, unless there is a comparable educational experience at each institution.
- d. Have a designated base institution that is responsible for the administration and core education of the program.
- The program director must be privileged and spend sufficient time at all e. participating institutions.
- 2. Have all residents follow an acceptable confirmed schedule for rotations with a minimum of fifty percent (50%) of the time spent being at the core institution.

3. Provide adequate scope and variety of training to all radiation oncology residents in the consortium.

STANDARD IV **PROGRAM REQUIREMENTS AND CONTENT**

INTRODUCTION Α.

The radiation oncology program shall adhere to a four-year curriculum that meets or exceeds the requirements listed within this document and prepares the resident for specialty certification in radiation oncology through provision for a combination of didactic and clinical training opportunities in both pediatric and adult patients. The program must provide an environment which is conducive to resident education. This environment must include exposure to both the clinical applications of radiation oncology as well as the skills necessary to develop the proper attitudes towards patients, professional staff, and administration of the institution.

Β. GENERAL COMPETENCIES

Programs must define the knowledge, skills, behaviors and attitudes required and provide educational experiences for residents to demonstrate competency within the following:

- Patient Care •
- Medical Knowledge

Practice-Based Learning and Improvement

- Interpersonal and Communication Skills •
- Professionalism
- System-Based Practice
- Osteopathic Philosophy and Osteopathic Manipulative Treatment

C. DIDACTIC

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Each area of training must have appropriate reading assignments. 1.

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The didactic component of instruction will include:

a. Advanced training in the basic sciences, which shall include didactic learning and clinical experiences (i.e., anatomy, physiology, drug interactions, allergic reactions, etc).

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b. Instruction in all allied basic sciences pertinent to radiation oncology including radiation physics, radiation dosimetry, radiation biology and knowledge of computer based planning system pertaining to the use and measurement of radioactivity including treatment planning and pathology with emphasis on neoplasms and medical statistics.

- c. Documented training in radiologic physics, radiation biology, radiation protection and basic radioisotope handling techniques under the direction of a qualified radiation physicist to meet current Nuclear Regulatory Commission (NRC) licensure requirements.
 - d. Regularly scheduled journal club.
 - e. Exposure to issues which the resident will face as a practicing clinician, including health policy, managed care, health administration, medical ethics, medical liability and practice management.
 - f. Instruction by the department of radiation oncology as well as integration of training with other departments, in the relationship of clinical radiation oncology with other departments such as surgery, pathology, medicine and pediatrics.
 - g. Opportunities for the resident to follow patients to surgery for the purpose of correlating radiologic findings and to follow cases to pathology to develop an understanding of the gross pathology of surgical specimens.
 - h. The resident shall review gross and microscopic findings of tissue in cases of special interest to the department of radiation oncology, attend autopsies, especially those of interest to the department of radiation oncology and participate in clinicopathologic and tumor conferences.
- 3. Academic study and practical experience that allows the resident to develop a thorough knowledge in the performance of radiation oncology procedures as well as the surgical and medical skills to safely perform the procedures and treat potential complications.
- 4. There shall be inter-departmental conferences and didactic lectures utilizing a prepared schedule or didactic lectures that must include lectures provided by the attending faculty and include outside faculty as well.
- 5. Residents must be excused from clinical duties to attend planned educational experiences.

D. CLINICAL COMPONENTS

- 1. The paramount allied clinical fields of diagnostic radiology, oncological surgery, pediatric oncology, cancer chemotherapy and immunotherapy, knowledge and use of radiopharmaceuticals, gynecological oncology, head/neck oncology and pathology. The resident should become familiar with the methods, techniques, and results in these fields.
- 2. Patient material of sufficient magnitude to provide a broad experience in the actual treatment and follow-up of the various types of cancer amenable to radiation therapy.
- 3. Experience in the use of all accepted modalities of radiation oncology in the treatment of the various types and locations of cancer and including a minimum of 8 intracavitary and 8 interstitial brachytherapy implants as the primary assistant per residency.
- 4. Cooperative efforts with other medical, surgical and ancillary disciplines conducive to a broad knowledge and understanding of the utilization and performance of radiation oncology. Six months during a four (4) year program shall be allowed, without distracting from the core program, to enable the resident to gain experience from other allied medical specialties to include a 2-month rotation in medical oncology, to include

adult and pediatric patients, and exposure to oncologic pathology and diagnostic imaging by a 1-month rotation for each discipline and 1 month in pediatric radiation oncology.

- An opportunity throughout for exposure to issues which the resident will face as a 5. practicing clinician, including health policy, managed care, health administration, medical ethics, medical liability and practice management.
- 6. Training for the therapeutic use of radiopharmaceuticals shall in addition to the specified physics and protection hours required by the AOA/AOBR basic standards include supervised clinical experience under the supervision of an authorized user at a medical institution that includes at least:
 - a. Supervised clinical experience under the supervision of an authorized user that includes the use of strotium-90 or current isotope for its use and application in the treatment of osteomatosis.
 - b. Supervised clinical experience under the supervision of an authorized user that includes the use of immunotherapy for the treatment of lymphoma and gastrointestinal malignancies.
 - 7. Each resident must have training in basic life support, and training in advanced cardiac life support is highly recommended (or per institutional requirements).
- **RESIDENT RESEARCH** E.

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During their training, each resident must participate in an investigative project under faculty supervision. This may take the form of laboratory research, clinical research, or the retrospective analysis of data from patients. The results of such projects shall be suitable for publication and presentation at local, regional or national scientific meetings and may be utilized to meet the requirement for exhibition at an AOCR Annual Convention.

> STANDARD V FACULTY AND ADMINISTRATION

A. PROGRAM DIRECTOR POSITION

The sponsoring institution shall designate an osteopathic radiation oncologist as program director for the program who has sufficient clinical time for program administration and clinical instruction. Appointments are subject to the approval of the American Osteopathic College of Radiology (AOCR) and subsequent registry by the AOA.

1. The program director of the radiation oncology residency training program must possess the following qualifications: $\sim 10^{-10}$

- Be certified as a radiation oncologist by the AOA, through the AOBR. a.
- b. Be a full-time radiation oncologist, capable and interested in conducting a broad program in radiation oncology, and spend sufficient time at the primary training site to adequately administer and supervise the program.
 - Shall meet the continuing medical education requirements of the AOA and the с. uista en la AOCR.
 - Meet the standards of the position as formulated in the AOA Basic Documents d. for Postdoctoral Training.

- Membership in the American Osteopathic College of Radiology
- Involvement in research and academic pursuits.

2. The program director shall have the following responsibilities:

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Preparation of a written statement outlining the curriculum and educational goals and objectives of the program with respect to knowledge, skills, and other attributes of residents at each level of training and for each major rotation or other program assignment. This statement must be distributed to residents and members of the teaching faculty and maintained through periodic review and updating. It should be readily available for review.

Update annually the residency program manual and shall distribute the residency program manual to each resident at the commencement of his/her residency training program.

Prepare and implement, with the assistance of the faculty, a comprehensive, wellorganized, and effective curriculum, both academic and clinical, which includes the presentation of core specialty knowledge supplemented by the addition of current information. This program design and structure of educational experiences will be reviewed and approved as part of the AOA accreditation process.

d. Provide the resident with all documents pertaining to the training program as well as the requirements for the satisfactory completion of the program.

e. Must establish an attendance policy for all scheduled conferences and maintain a record of attendance for all lectures, journal club, etc.

f. Ensure that appropriate formal consortium or affiliation institutional and educational agreements for outside rotations necessary or desirous to meet the program objectives are executed and on file.

g. Evaluate the residents, faculty, and the radiation oncology residency program and submit the required reports to the responsible parties as outlined by the American Osteopathic Association.

h. Submit at a minimum, a quarterly resident evaluation to the director of medical education (DME). Evaluations must be signed by both the resident and the program director and become part of the resident's record and the Program's files. Annual reports shall be submitted to the AOCR. The program director should ensure that a certificate of completion or letter of verification of completion is submitted by the DME to the AOCR. The institution shall retain copies of all required reports.

i. Supervision of residents through explicit written descriptions of supervisory lines of responsibility for the care of patients. Such guidelines must be communicated to all members of the Program faculty. Residents must be provided with prompt, reliable systems for communication and interaction with supervisory physicians. A faculty Radiation Oncologist must be available at all times for consultation with the resident.

In coordination with the DME, the program director has the responsibility for all schedules and allowance for appropriate time for residency training, including lectures, educational sessions, and study time.

Working with the DME, the program director supports the predoctoral and postdoctoral education and training at the institution.

1. Notifies the AOCR of all residents enrolled in the training program on an annual basis.

m. Obtains documentation of resident evaluation on all outside rotations.

Ensure that the program complies with the standards, policies and procedures of the AOA.

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- Prepare for and participate in the AOA evaluation of the program in cooperation 0. with the Division of Postdoctoral Training and the designated evaluator.
- Ensure that residents complete AOCR required examinations and submit results p. to the AOCR.
- Inform the AOA, OPTI and AOCR of major changes in the program, including **q**. 🦈 but not limited to, changes in program directors, institutional ownership and affiliation, radiation oncology department staff or other major administrative changes. Any organizational or structural change that may affect a residency training program must be approved in writing by the AOCR prior to implementation. Requests for change must include the educational impact of any request and documentation that the educational process will not be compromised by said change.
- Participate on AOCR Program Director Conference calls or ensure an appropriate r. designee will be present to participate and disseminate information.

Attend program directors meetings as required by the AOCR to facilitate s. Program Director and Faculty development activities.

B. FACULTY

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- The sponsoring institution, in conjunction with the program director shall appoint a 1. minimum of two(2) core faculty who shall participate in the radiation oncology residency program.
 - Faculty members must be certified in radiation oncology by either the AOA through the American Osteopathic Board of Radiology (AOBR) or by the American Board of Radiology (ABR) or an active candidate in the process of certification by the AOBR or the ABR and to also include recertification within the prescribed time frame of the certifying body (certification in radiology by either board would be acceptable). Credentials must be retained on file and available to the on-site evaluator.

Core faculty must be provided with sufficient non-clinical time to provide **b.** instruction to residents and perform periodic resident and Program evaluation. Paris a mes Additionally, all appointed faculty must regularly participate in the academic education program, with documented participation in formal lectures, case conferences, journal clubs and mock board review.

c. Faculty must participate in regional or national professional and scientific societies continuing medical education programs, and are encouraged to make presentations at the organizations' meetings.

d. Guidance and technical support (e.g., research design, statistical analysis) should a strain strain the offered to residents involved in scholarly activity.

e. Count tenens radiation oncologists cannot qualify as core faculty members.

- The institution shall have administrative and other non-physician staff committed to the ····2. program to support teaching in the radiation oncology residency program. en en la compañía de la compañía de
 - Faculty must adhere to institution specific code of ethics and AOA code of ethics. 3. The structure of a second provided and a significant second state of the last of the last of the
 - 4. The teaching faculty must be organized and have regular documented meetings to review the goals and objectives as well as program effectiveness in achieving them. At least one resident representative should participate in these reviews. 111 ž,
 - There must be timely and effective feedback to residents on their performance. 5.

and the strange Faculty is required to supervise the resident in their daily duties in accordance with the programs supervision policy.

- a. The residency is an educational experience and must be designed by the institution to offer structured and supervised exposure to promote learning rather than service. An opportunity must exist for residents to be supervised and evaluated throughout their 1. . . . s training with availability of teaching staff scheduled within the program. Residents State of the State will be responsible to attending physicians for assignment of responsibility.
- b. A radiation oncologist must be on call with the resident and must assume ultimate responsibility for all actions of the resident(s) under his/her supervision. Specific responsibilities shall be delegated at the discretion of the institution and/ or department. a second
 - c. Residents shall be given gradual increases in their responsibility, commensurate with their ability. If the appropriate the second s 18 1 A.
 - d. Continuity of care during the residency shall be endured by proper communication between night and day shift residents and attending physicians. Morning reviews of important, interesting and critical cases shall occur daily.

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Α. An applicant for radiation oncology residency training must:

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- Be a graduate of an AOA-accredited college of osteopathic medicine and have 1. successfully completed an AOA-approved internship.
- 2. Be and remain a member of the AOA and the AOCR during residency.
- Be appropriately licensed in the state in which training is conducted. 3.
- 4. Arrange for the provision of official transcripts by the College of Osteopathic Medicine and Hospital Administration of internship and/or previous residency training.
- Sign an annual residency contract with the institution 5.
- Be a full-time resident of the training institution; must not be engaged in any other 6. residency training program.
- The resident is legally, morally, and ethically responsible to pursue exclusively the agreed upon Β. program of training. The resident shall not engage in any outside activities of a professional nature during residency training except those approved by the program director and designated institutional authorities. Such activities must not interfere with the resident's participation in the training program. The resident may not act as an unsupervised consultant in radiation oncology and must be designated in such a manner to retain his/her identity as a resident.
- С. The resident shall progressively assume increasing responsibility for patient care during the residency program, so that by the senior year, the resident must be able to assume complete management of all assigned cases.
- Increased competency in radiation oncology is based on experience and number and variety of D. cases managed in the radiation oncology department. Such experience is gained through participation in highly specialized rotations as deemed necessary by the program director. It is required that by the completion of a four-year radiation oncology residency program, each resident will have participated in organized rotations as defined in Curriculum and Instruction. ender in einstelligt eine eine eine der der eine eine einstelligten einer ein

- E. Shall adhere to established policies and procedures for residency training, as outlined in the AOA <u>Basic Documents for Postdoctoral Training</u>, this document, and in the institution's resident manual and the residency program manual.
- F. The resident shall maintain formal records of all activities related to the educational program. These records shall be submitted monthly to the program director and DME for review and verification. Copies of these records shall be kept on permanent file by institution and shall be available at the time of the inspection. These records should document the fulfillment of the requirements of the program, describing the volume, variety and scope, and progressive responsibility on the part of the resident for radiation oncology cases and procedures performed under supervision. The log shall include a report of all patients seen in consultation and organ systems involved and activities of the resident as well as meetings attended, reading assignments, conferences, etc. Documentation should include brachytherapy log.
- G. The resident is responsible to participate in education activities and opportunities that address ethical behavior as formulated by the program, especially the ethical dimensions of the practice of medicine.
- H. Residents in the program will learn teaching skills by actively participating in the process of instructing interns, medical students and other residents.
- I. The resident must submit an annual report to the AOCR and the DME. An annual report must be evaluated as a twelve (12)-month period of residency training that must be under contract with a single institution. A certificate of completion must be submitted with the final year's annual report in order to be considered for program completion approval.
- J. The resident must present one exhibit at an Annual Convention of the AOCR no later than the Annual Convention of the resident's third year of training. An abstract of the exhibit is due by January 15 of the resident's second year of training. The abstract must be submitted according to the AOCR's Guidelines for Resident Scientific Exhibits.
- K. Participate in radiation oncology related and other conferences including journal club.

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- L. Must complete all AOCR requirements as well as any additional requirements of the individual residency training program or the OPTI each year prior to AOCR approval for that year of training. Residents in a consortium must submit verification of completion of training from the consortium.
- M. First, second and third year residents must participate in the ACR In-Training Examination and submit results to the AOCR.
- N. Duty hours in the program must be educationally oriented. As outlined in the AOA <u>Basic</u> <u>Documents for Postdoctoral Training</u>, the following duty hours must be followed during the training program:
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a. The resident shall not be assigned to work physically on duty in excess of eighty hours (80) per week averaged over a four (4) week period, inclusive of in-house night call.

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b. The resident shall not work in excess of twenty-four (24) consecutive hours inclusive of morning and noon educational programs. Allowance for, but not to exceed up to six (6) hours for inpatient and outpatient continuity, transfer of care,

educational debriefing and formal didactic activities may occur. Residents may not assume responsibility for a new patient after twenty-four (24) hours.

If moonlighting is permitted, all moonlighting will be inclusive of the eighty (80) hour per week maximum work limit and must be reported.

The resident shall have alternate week forty-eight (48) hour periods off or at least one (1) twenty-four (24) hour period off each week.

Upon conclusion of twenty-four (24) hour duty shift, residents shall have a minimum of twelve (12) hours off before being required to be on duty again. Upon completing a lesser hour duty period, adequate time for rest and personal activity must be provided.

All off-duty time must be totally free from assignment to clinical or educational activity.

Those rotations requiring the resident to be assigned to emergency department duty shall not be assigned longer than twelve (12) hour shifts.

The resident and training institution must always remember the patient care responsibility is not precluded by this policy. In the case where a resident is engaged in patient responsibility which cannot be interrupted, additional coverage should be provided to relieve the resident involved as soon as possible. The resident may not be assigned to call more often than every third night averaged over any consecutive four (4) week period.

j. The training institution shall provide an on-call room for residents, which is clean, safe, quiet and comfortable, so to permit rest during call. A telephone shall be present in the on-call room. Toilet and shower facilities should be present in or convenient to the room. Nourishment shall be available during the on-call hours of the night.

k. When residents take call from home and are called into the hospital, the time spent in the hospital must be counted toward the weekly duty hour limit.

2. MOONLIGHTING POLICY

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Any professional clinical activity (moonlighting) performed outside of the official residency program may only be conducted with the permission of the program administration (DME/Program Director). A written request by the resident must be approved or disapproved by the Program Director and DME and be filed in the institution's resident file. All approved hours are included in the total allowed work hours under AOA policy and are monitored by the institution's graduate medical education committee. This policy must be published in the institution's housestaff manual. Failure to report and receive approval by the program may be grounds for terminating a resident's contract.

STANDARD VII EVALUATION

The program must demonstrate an effective plan for continuous improvement of resident performance and competency utilizing regular assessments of the residents, faculty and the program.

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A. RESIDENT EVALUATIONS

1. Individual Rotation Evaluations

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The program director or designated faculty member will complete written evaluations of resident performance on a rotation or a monthly basis. These evaluations should utilize methods to accurately assess resident's competence in patient care, interpersonal and communication skills, systems-based practice, medical knowledge, practice-based learning and improvement, professionalism, and osteopathic manipulative theory. This must include evaluations from all affiliated training sites and supplemented rotation sites.

2. Quarterly Evaluation

Completed performance evaluations must be shared by the program director with the resident at least quarterly or more frequently if a resident's performance is substandard.

3. Annual Evaluation

The resident may progress on to the next year of training only after satisfactory performance in all rotations and in the core competencies as documented in the annual report.

4. The program director must document that residents needing remediation or counseling as a result of evaluation are given it in a timely manner. There must be documentation of follow up evaluations of these residents.

5. Final Evaluation

Upon successful completion of the program, a final evaluation will be performed for each resident by the program director and be maintained by the institution in the resident's permanent file. A copy will also be sent to the AOCR office. This final evaluation will attest to the resident's professional abilities and competency at graduation to independently practice radiation oncology.

6. All evaluations must be signed by the program director (or designated faculty on individual rotation evaluations) and the resident to document that evaluation and counseling have occurred as required. Copies of evaluations should be made available to the resident.

B. FACULTY EVALUATION

- 1. The program director and program faculty should be peer evaluated at least annually for their teaching, scholarly activities, and development of the program.
- 2. The resident shall complete an evaluation of the rotation and faculty at the completion of each rotation. The evaluations must be processed in a cumulative manner to protect the confidentiality of the resident and reported to the faculty on an annual basis.

C. PROGRAM EVALUATION

- 1. There will be a program evaluation committee consisting of the program director, one faculty member and the chief resident to prepare an evaluation of the program at least annually and prepare a report as a method for revision and updating of the program.
- 2. Program assessments and measured outcomes for continuous quality improvement should be done on an on going basis, with an annual summative evaluation of the quality of the program. Evaluative information should be used for program improvement, and documentation should be on file

- 3. Multiple measures should be used for program review and evaluation to obtain a comprehensive view of program quality. Recommended methods include performance on certifying examination; post graduate professional performance satisfaction surveys; resident persistent rate in the program; percent of graduates completing the program on time; placement of graduates; professional accomplishments of program graduates.
- 4. All program directors shall use the results of the ACR In-Training examination to improve their individual programs; they shall also make the results available to the AOCR and residency inspectors along with the improvements they have made to their program as a result thereof. The program director will make results available to the director of medical education
- 5. To have 100% of graduates participate in the AOBR examination process by completion of residency training. During the most recent 5-year period, at least 50% of its graduates should pass without condition the written and oral examination on the first attempt.

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Basic Standards for Residency Training in Radiation Oncology

Appendix I

Core Competency of Medical Knowledge for Radiation Oncology

DEFINITION

Residents are expected to demonstrate and apply knowledge of accepted standards of clinical medicine as it applies to the practice of radiation oncology; remain current with new developments in medicine, specifically as applicable to the specialty of radiation oncology, and participate in lifelong learning activities, including research.

REQUIRED COMPETENCIES

- Demonstrate sufficient knowledge of medicine and apply this knowledge to radiation oncology in a clinical context to administer meaningful therapeutic plans.
- Demonstrate progressive acquisition of radiation oncology.
- Demonstrate knowledge of the principles of research design and implementation
- Generate a clinically appropriate treatment plan.
- Demonstrate the ability to use all relevant information resources to acquire evidence-based data
- Understand the principles of proper therapy equipment calibration and operation to safely practice radiation oncology.

SUGGESTED EDUCATIONAL CONTENT

- Didactic lectures and self-directed learning on the science and practice of radiation oncology
- Participation in departmental and inter-departmental case conferences
- Participation in the clinical activities of the radiation oncology department
- Departmental or institutional training programs on research design and implementation

SUGGESTED METHODS FOR EVALUATION

- Global ratings by faculty
- Program-developed written and/or computer generated examinations
- ACR In Training examination
- AOBR Physics examination
- AOBR Radiobiology examination
- AOBR Clinical examination
- Radiation Oncology Oral AOBR examination
- Raphex physics examination

Appendix II

Core Competency of Osteopathic Philosophy and Osteopathic Manipulative Treatment for Radiation Oncology

DEFINITION

Residents are expected to demonstrate and apply knowledge of osteopathic manipulative treatment (OMT) and principles appropriate to the specialty of radiation oncology.

REQUIRED COMPETENCIES

- Demonstrate an understanding of osteopathic principles and OMT, especially their role in the medical practice of referring physicians
- Understand and integrate osteopathic principles and philosophy into all clinician and patient interactions and activities

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• Demonstrate knowledge of OMT procedures applicable to treating cancer or therapy complications.

SUGGESTED EDUCATIONAL CONTENT

- Didactic activities
 - Lectures
 - Reading assignments
- CME Programs
- Clinical rounds with OMT practitioners treating appropriately related symptomatology

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SUGGESTED METHODS FOR EVALUATION

- Objective written testing of knowledge
- Direct observation of OMT skills by competent observers