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PDR 004

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

AUG 2 0

MEMORANDUM FOR: Emile Julian, Chief
Docketing and Services Branch, SECY

FROM: Sher Bahadur, Chief
Regulation Development Branch, DRA, RES

SUBJECT: FORWARDING A PUBLIC COMMENT TO BE DOCKETED

Enclosed is a letter (with attachments) dated August 9, 1993, from Dr. Joan P. Porter of the National Institutes of Health. This letter contains her comments on a proposed rule entitled "Preparation, Transfer for Commercial Distribution, and Use of Byproduct Material for Medical Use" (58 FR 33396; June 17, 1993).

Please docket this letter as a public comment for the proposed rule. I would appreciate your sending me a copy of the docketed letter.

Sher Bahadur

Sher Bahadur, Chief
Regulation Development Branch
Division of Regulatory Applications
Office of Nuclear Regulatory Research

Enclosure:
Letter from Joan P. Porter w/att.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

005

August 9, 1993

TO: Dr. Anthony N. Tse
Office of Nuclear Regulatory Research
U.S. Nuclear Regulatory Commission

FROM: Senior Policy Analyst
Office for Protection from Research Risks

SUBJECT: Nuclear Regulatory Commission Comments on June 17 Proposed Rules "Preparation, Transfer for Commercial Distribution, and Use of Byproduct Material for Medical Use" (58 FR 33396)

Thank you for sending copies of the proposed rule. I have distributed them to all members of the Human Subjects Research Subcommittee for comment to my office or directly to you.

The Office for Protection from Research Risks (OPRR) has several comments on the proposed rule:

1. We find it appropriate to modify the word "patient" to include patient or human research subject (10 CFR Part 35).

2. Section 35.6. What provisions for human subjects protections are there if the research is not conducted, supported, funded or regulated by another federal agency? Will you have any checks to determine if the Federal Department or Agency has, in fact, implemented the Federal Policy for byproduct-related research involving human subjects?

The proposed rule indicates that if the Federal Policy is not applicable, the Nuclear Regulatory Commission (NRC) will require licensees to apply for and obtain approval of a specific amendment to its NRC license prior to conducting research using byproduct material and involving human subjects.

The proposed rule states that the NRC would ensure that the proposed research would receive approval of the IRB and obtain the human subjects' informed consent. We note that the IRB requirements in the Federal Policy are quite specific regarding authority functions and composition of the IRB. Some institutions have "IRBs" but they do not function nor are they composed as described in the Federal Policy. Likewise, the minimal required elements of informed consent are described in some detail in the Federal Policy. NRC should take steps to

ensure that all provisions of the Federal Policy are met. These go beyond identification of an IRB and informed consent for subjects. NRC should consider issuing license amendments which include provisions similar to single project assurances or cooperative project assurances issued by OPRR, for example, which will document that all aspects of the Federal Policy apply to the research conducted. A sample is enclosed.

A technical point: The Federal Policy does not refer to "letters" of assurance, but assurances of compliance. The assurances are formal documents that are negotiated between the Federal funding agency (e.g., OPRR for the Department of Health and Human Services) and the institution in which the research is to be conducted. The minimal requirements for the assurance document are described in the Federal Policy at Section 103.

In sum, we recommend that NRC adopt the assurance mechanism to cover research not already subject to the Federal Policy. Such an assurance statement could be incorporated into the license amendment. Otherwise, a dual standard of protection of research subjects could result in which institutions not governed by the Federal Policy could utilize less extensive human subject protections. We suggest that a system that relies solely on NRC inspection after the research is conducted in the absence of prospectively negotiated assurance in which responsibilities are clearly described could well result in misapplication or non-conformance with Federal Policy requirements.

I would be pleased to discuss this information with you in more detail and to supply additional descriptive documents. Please contact me on 301-496-7005 or at the address above.

Joan P. Porter

Joan P. Porter, D.P.A.

Enclosure

cc: Dr. Ellis

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PDR

AOCR

AMERICAN OSTEOPATHIC COLLEGE OF RADIOLOGY

115 EAST SECOND STREET
MILAN, MO 63556-1201

1-800-256-2627
(816) 265-4011
FAX (816) 265-3484

January 7, 1994

Mr. Anthony Tse
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Dear Mr. Tse

Thank you for contacting me regarding documentation to support our request to include certification by the American Osteopathic Board of Radiology in specific areas in Part 35 Medical Use of Byproduct Material in the United States Nuclear Regulatory Commission Rules and Regulations.

Enclosed are the following documents:

1. Basic Standards for Residency Training in Radiation Oncology

2. General Information for Candidates - Radiation Oncology Certification Examination

If further information is required, please do not hesitate to contact me.

Sincerely

Pamela A. Smith

Pamela A. Smith
Executive Director

PAS/dp

cc Ferdinand L. Manlio, D.O., President

GENCORR/TXTDP

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RADIATION ONCOLOGY CERTIFICATION EXAMINATION
GENERAL INFORMATION

SECTION 1. ELIGIBILITY REQUIREMENTS

The minimum requirements to be eligible to receive certification in Radiation Oncology from the AOA through the American Osteopathic Board of Radiology are as follows:

A. The applicant must be a graduate of an AOA accredited college of osteopathic medicine.
B. The applicant must be licensed to practice in the state or territory where his/her practice is conducted.
C. The applicant must be able to show evidence of conformity to the standards set forth in the Code of Ethics of the American Osteopathic Association.
D. The applicant must have been a member in good standing of the American Osteopathic Association or the Canadian Osteopathic Association for the two (2) years immediately prior to the date of certification.
E. The applicant must have satisfactorily completed a one-year AOA approved internship.
F. A period of three (3) years or more of AOA approved training in radiation oncology shall be required after the required one (1) year of internship.

SECTION 2. APPLICATION REQUIREMENTS

A. An application, two letters of recommendation, application fee, and copy of current AOA membership card must be on file with the executive director and approved by the credentials committee by January 1 of the year in which the candidate begins the examination process. All materials submitted by the applicant shall remain the property of the Board.
B. The applicant shall provide letters of recommendation from two (2) diplomates of the Board who are personally acquainted with the applicant and who will vouch for his radiological training and experience, personal character, and who have personally observed the radiological skill of the applicant. The sponsors shall send their letters of recommendation directly to the executive director of the Board.

SECTION 3. TRAINING REQUIREMENTS

The candidate shall provide documentary evidence of the required minimum number of years of AOA approved residency training in the specialty for which certification is being sought. This specialty training shall include:

A. Advanced study in the sciences: anatomy, physiology, biochemistry, pathology, pharmacology, radiophysics, radiobiology, and such other basic sciences as are necessary to a mature and comprehensive understanding of the prevention, diagnosis, therapy, and management of the disorders involved in radiology.

B. Active experience in the diagnosis and treatment in such amount and diversity that it will assure adequate training in the specialty.

SECTION 4. EXAMINATIONAL REQUIREMENTS

A. Following satisfactory compliance with the prescribed requirements for examination, the applicant is required to pass appropriate examinations planned to evaluate an understanding of the scientific basis of the problems involved in radiation oncology; familiarity with the current advances in radiation oncology; possession of sound judgment; and of a high degree of skill in the diagnosis and therapeutic procedures involved in the practice of radiation oncology.
B. The applicant shall present himself/herself for oral interview when requested to do so by the secretary-treasurer, upon recommendation of the Credentials Committee.
C. The applicant shall appear for oral and written examination at the time and place designated.
D. The applicant is eligible for reexamination after failing all or part of the examination not to exceed two additional examinational sessions within the board eligibility period.

SECTION 5. EXAMINATION PROCESS

There are two parts to the examination process. They are:

1. Written
2. Oral Film Interpretation

A. WRITTEN EXAMINATION

The written examination will include the following subjects:

1. Cellular Radiobiology
2. Head and Neck
3. Colorectal and Anus
4. Genitourinary Tract
5. Sarcoma and Primary Bone Tumors
6. Central Nervous System
7. Oncologic Emergencies
8. Lung and Mediastinal Tumors
9. Breast
10. Esophagus, Stomach, & Intestine
11. Prostate
12. Gynecology Oncology
13. Pediatrics
14. Lymphoma
15. Physics
16. Treatment Planning
17. Chemotherapy
18. Nuclear Therapy
19. Skin
20. Brachytherapy
21. Radiation Protection

The written examination will be conducted in two sessions. Session I will be conducted on Saturday, October 8, and Session II will be conducted on Sunday, October 9. The examination on the first day will be 3 hours in lergth and will include approximately 120 questions. The examination on the second day will be 1 1/2 hours in length and will include approximately 60 questions. The format will include both multiple choice and true and false questions. True and false questions will count 1/2 point and multiple choice questions will count 1 point in the scoring process. No break will be scheduled either day of the examination. Only one candidate will be allowed to leave the examination room at any time.

The written examination will be supervised by proctors who are responsible to the Board and empowered by the Board to ensure that the examination is conducted ethically and in accordance with the Rules of the Board. Candidates are not permitted to bring into the examination any notes, textbooks or other reference materials. No scratch paper is permitted. Although the form of questions will be such that a calculator is unnecessary, candidates will be permitted to use a digital but not a programmable calculator.

Any candidate who exhibits irregular behavior such as copying answers, using notes etc. will be reported to the Board. The examinations are the sole property of the American Osteopathic Board of Radiology and must not be removed from the test area or reproduced.

1. The written examination will be given in two sessions. The first session will be 3 hours in length; the second session will be 1 1/2 hours in length.

2. A candidate must pass the written examination to be permitted to sit for the oral examination.

3. The minimum passing grade on the total overall examination is 70%.

4. A candidate will have three opportunities to successfully complete the written examination within the period of board eligibility.

B. ORAL FILM INTERPRETATION

All candidates will be examined in the following subjects:

1. Cellular Radiobiology
2. Head and Neck
3. Colorectal and Anus
4. Genitourinary Tract
5. Sarcoma and Primary Bone Tumors
6. Central Nervous System
7. Oncologic Emergencies
8. Lung and Mediastinal Tumors
9. Breast
10. Esophagus, Stomach, & Intestine
11. Prostate

12. Gynecology Oncology
13. Pediatrics
14. Lymphoma
15. Physics
16. Treatment Planning
17. Chemotherapy
18. Nuclear Therapy
19. Skin
20. Brachytherapy
21. Radiation Protection

1. All candidates will be examined for a period of 1 1/2 hours at each of the 3 oral stations.

2. A candidate will be identified by his/her first name and AOA number only. Candidates are instructed not to discuss their training or practice institutions with the examiner.

3. A candidate must receive a passing score of 70% to pass the examination.

4. A candidate will have three opportunities to successfully complete the oral film interpretation examinations within the period of board eligibility.

SECTION 6. CERTIFICATION

1. A candidate will be recommended for certification in Radiation Oncology upon successful completion of the written and oral examinations.

SECTION 7. REEXAMINATIONS

1. The fee for a candidate who fails the written examination or the oral examination in Radiation Oncology is $600.

2. A candidate has three opportunities in which to complete the written examination process and three opportunities in which to complete the oral examination process within the period of board eligibility. Board eligibility shall terminate on December 31 of the sixth year following the year eligibility is established.

3. A request for reexamination must be submitted in writing to the American Osteopathic Board of Radiology by the deadline established by the Board.

SECTION 8. APPEAL MECHANISM

1. If a candidate feels that the actions of this certifying board, with regard to any part of the examination, constitute unequal application of the regulations and requirements or standards, unwarranted discrimination, prejudice, unfairness or improper conduct of the examination, he/she has the right to appeal to the Board.

2. If the candidate is not satisfied with the results of an appeal before this Board, he/she has the right to further appeal to the Bureau for Osteopathic Specialists and the AOA Board of Trustees.

SECTION 9. REENTRY INTO THE CERTIFICATION PROCESS

1. A candidate who has lost board eligibility status and who wishes to reenter the certification process may submit, by individual petition, a request for such reentry to the executive director of the Board. If such petition is approved by the Board, the individual shall not be identified as board eligible.

2. The Board shall provide such candidate with a written list of deficiencies and, further, cooperate with the Committee on Evaluation and Educational Standards of the American Osteopathic College of Radiology in developing a training program designed to the individual's needs.

3. Such programs shall be reviewed and approved by the Committee on Evaluation and Educational Standards of the American Osteopathic College of Radiology. The committee must verify to this Board that the program has been conducted and successfully completed.

4. Upon documented completion of the approved program, the candidate may apply to take the certifying examination.

(1)

BASIC STANDARDS

FOR RESIDENCY TRAINING

IN

RADIATION ONCOLOGY

AMERICAN OSTEOPATHIC ASSOCIATION

and the

AMERICAN OSTEOPATHIC COLLEGE OF RADIOLOGY

AOCR/R-October 1992

AOA 1993

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BASIC STANDARDS FOR RESIDENCY TRAINING

IN

RADIATION ONCOLOGY

ARTICLE I - INTRODUCTION

These are the basic standards for residency training in radiation oncology as approved by the American Osteopathic Association (AOA) and the American Osteopathic College of Radiology (AOCR). These standards are designed to provide the osteopathic resident with advanced and concentrated training in radiation oncology and to prepare the resident for examination for certification in radiation oncology. (See Appendix I)

ARTICLE II - PURPOSES

The specialty of radiation oncology consists of the treatment of human disease by the use of sources of ionizing radiation both naturally occurring and artifically produced and includes radionuclides and radionuclide tagged agents. Further, it includes treatment of tumors with radiation protective agents, radiation sensitizing agents, and other modalities in combination with radiation. The purposes of an osteopathic radiation oncology training program are to:

A. Properly train the resident in the observation and correlation of neuromusculoskeletal lesions as they apply to the diagnosis and therapeutics of disease and its application to the osteopathic concepts in the practice of radiation oncology.

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B. Provide continuity of didactic and clinical experiences which will enable the resident to become proficient in radiation oncology skills.

C. Introduce the resident to basic and clinical research.

ARTICLE III - INSTITUTIONAL REQUIREMENTS

A. To be approved by the AOA for residency training in radiation oncology, an institution* must meet all the requirements as formulated in the Residency Training Requirements of the AOA.

B. The institution must provide sufficient patient load to properly train a minimum of two (2) residents in radiation oncology. The minimum staff/resident ration is 1:2. The number of residents can not exceed the number of radiation oncologists by greater than one. Patient case load should be of sufficient magnitude to provide a broad experience in consultation, actual treatment, and followup of the various types of cancer amenable to radiation therapy. Minimum number of new treated patients shall be 200 per resident, per year.

C. The institution offering the residency must have active programs in cancer surgery and cancer chemotherapy as well as radiotherapy.

D. The department shall have an adequate record system for all cases in which consultation, therapy, and follow-up care has been provided and a satisfactory pathologic cross file index using standard disease nomenclature.

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*Hospital, college, consortium, organization or other training facility.

(10)

E. The institution shall maintain an adequate medical library containing carefully selected texts, medical journals and other appropriate publications, covering the fields of radiation oncology, oncology, radiology, pathology and other current texts in 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.

F. The institution's radiation therapy equipment shall be of modern design and shall meet the requirements and standards of federal, state and local regulations. Equipment must be available for supervoltage teletherapy. A sufficient amount of radium or its equivalent should be available along with a variety of applicators for both interstitial and intracavitary brachytherapy. Training must include use of linear accelerators with electron capability as well as current treatment planning and computerized dosimetry equipment.

G. The institution must have a full-time radiological physicist and full or part-time dosimetrist.

H. The department should be physically arranged to provide adequate space and an atmosphere conducive to resident study and conferences.

I. The institution must provide a written policy and procedure for the selection of residents, as well as resident discipline and dismissal.

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J. The institution shall execute a contract with each resident in accordance with the Residency Training Requirements of the AOA.

K. Upon satisfactory completion of the training program, the institution shall award the resident an appropriate certificate. 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).

ARTICLE IV - PROGRAM REQUIREMENTS

A. The residency training program shall only commence after it has received the recommendation of the Committee on Postdoctoral Training and the approval of the AOA Board of Trustees.

B. The residency training program in radiation oncology shall consist of a minimum of three (3) years of concentrated study after satisfactory completion of an internship year.

C. The general educational content of the program shall include:

1. Osteopathic concepts as they apply to the practice of radiation oncology.

2. All allied basic sciences pertinent to radiation oncology including radiation physics, radiation dosimetry, radiation biology and pathology with emphasis on neoplasms and medical statistics. Radiation physics and radiation biology including treatment planning and dosimetry may be taught in the form of didactic lectures, seminars and practical laboratory exercises. These are to include training in basic radioisotope handling techniques under the direction of a

qualified radiation physicist (200 hours) and must comply with any current nuclear regulatory commission requirements for training to allow the utilization of radioactive materials.

a. Radiation physics and instrumentation (110 hours)

b. Radiation protection (40 hours)

c. Mathematics pertaining to the use and measurement of radioactivity (25 hours)

d. Radiation biology (25 hours)

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. The paramount allied clinical fields of diagnostic radiology, oncological surgery, pediatric oncology, cancer chemotherapy, gynecological oncology, head/neck oncology and pathology. The resident should become familiar with the methods, techniques, and results in these fields.

5. Patient material of sufficient magnitude to provide a broad experience in the actual treatment and followup of the various types of cancer amenable to radiation therapy.

6. 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 30 intracavitary and 10 interstitial brachytherapy implants as the primary assistant per residency.

7. 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 three year program shall be allowed, without distracting from the core program, to enable the resident to gain experience from other allied medical specialties.

8. A log of his/her training program shall be maintained and reported annually to the program director. 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.

9. Participation by the resident in teaching conferences within the department as well as within the institution embodying the application of special radiation oncology studies.

10. Research. Retrospective or prospective studies should be performed in cooperation with the program director and where required, approved by institutional review authorities. The research project may be utilized in the writing of one of the required scientific paper or exhibit.

D. If necessary, the program must provide suitable arrangements for outside rotations to ensure the complete education of the resident and for broadening the scope of training. All rotations must meet standards as formulated in the Residency Training Requirements of the AOA and must be formally approved by the parent and host institutions.

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ARTICLE V - QUALIFICATIONS AND RESPONSIBILITIES OF PROGRAM DIRECTOR

A. Qualifications

1. The program director must be certified as a radiation oncologist by the American Osteopathic Association through the American Osteopathic Board of Radiology or other appropriate certifying board.
2. The program director shall be a full-time radiation oncologist, capable and interested in conducting a program in radiation oncology and shall meet the continuing medical education requirements of the AOA and the AOCR.
3. The program director must meet the standards of the position as formulated in the Residency Training Requirements of the AOA.

B. Responsibilities

1. The program director's authority in directing the radiation oncology training program must be defined in the program documents of the institution.
2. The program director shall arrange affiliations and/or outside rotations necessary to meet the program objectives.
3. The program director shall, in cooperation with the AOA Office of Osteopathic Education, prepare required materials for inspections, and shall document the postdoctoral training of all radiation oncologists in the department since the last inspection.

(15)

4. The program director shall provide the resident with all documents pertaining to the training program as well as the requirements for the satisfactory completion of the program.
5. The program director shall be required to submit quarterly program reports to the director of medical education. Quarterly reports must be signed by both the resident and the program director and become part of the resident's log and the department files. Annual reports shall be submitted to the AOCR. The program director shall retain copies of all required reports.

ARTICLE VI - RESIDENT REQUIREMENTS

A. Residents in radiation oncology must:
   1. Have graduated from an AOA accredited college of osteopathic medicine.
   2. Have completed a one (1) year AOA approved internship.
   3. Be and remain members of the AOA during residency training.
   4. Be appropriately licensed in the state in which training is conducted.

B. During the training program the resident must:
   1. Submit an annual log to the program director. Logs shall be signed by the program director and copies sent to the director of medical education. Logs shall include documentation of outside rotations.
   2. Submit an annual report to the American Osteopathic College of Radiology and the DME.

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3. Submit one scientific paper. approved and signed by the program director, to the American Osteopathic College of Radiology by March 1 of the second year of training (See Appendix II). One exhibit must be presented at an Annual Meeting of the American Osteopathic College of Radiology no later than the Annual Meeting of the resident's third year of training (See Appendix III).

4. Participate in radiation oncology related and other conferences whenever possible.

C. It is recommended that the resident apply for candidate membership in the American Osteopatic College of Radiology during the first year of residency training.

ARTICLE VII - POLICIES

A. Advanced Standing Policy.

To receive advanced standing in radiology, candidates must:

1. Have successfully completed at least one year of residency training in any specialty.

2. Submit documentation from previous program director(s) confirming that the candidate has achieved a specific level of training.

3. Receive an endorsement from the current program director recommending advanced standing for a specific block of time.

Requests for advanced standing, and time allotted for such requests will be considered on a case by case basis. The committee on evaluation and educational standards of the American Osteopathic College of Radiology (AOCR) will review all applications and make appropriate recommendations to its board of directors and other appropriate approval bodies.

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B. Resident Work Hours and Supervision Policy:

Work Hours:

1. The average number of work hours per week will not exceed 80 hours/week, unless superseded by federal, state and/or local regulations.

2. Since AOCR programs must have a minimum of 2 residents in training, residents will work no more than every other weekend on service.

   Daytime hours for residents may not exceed 14 hours/day. Residents are on call at night for emergencies only. Night call responsibility will be divided equally among the resident staff. The total number of hours will be included in the 80 hours/week.

3. Residents have an average of one day off per seven-day week.

4. Residents shall have a minimum of two weeks off, as vacation, unless superseded by federal, state and/or local regulations.

Supervision:

1. 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.

   All resident's dictation shall be checked and approved by attending radiation oncologist.

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2. Residents shall be given gradual increases in their responsibility, commensurate with their ability.
3. 'Moonlighting' shall be allowed only at the discretion and approval of the program director and the Director of Medical Education.
4. Continuity of care during the residency shall be ensured 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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ARTICLE VII - REQUIREMENTS FOR CERTIFICATION

Section 1. - Eligibility Requirements

The minimum requirements to be eligible to receive certification from the AOA through the American Osteopathic Board of Radiology are as follows:

A. The applicant must be a graduate of an AOA accredited college of osteopathic medicine.

B. The applicant must be licensed to practice in the state or territory where his/her practice is conducted.

C. The applicant must be able to show evidence of conformity to the standards set forth in the Code of Ethics of the American Osteopathic Association.

D. The applicant must have been a member in good standing of the American Osteopathic Association or the Canadian Osteopathic Association for the two (2) years immediately prior to the date of certification.

E. The applicant must have satisfactorily completed a one-year AOA approved internship.

F. A period of four (4) or more years of AOA approved training in diagnostic radiology shall be required, after the required one (1) year of internship for candidates commencing training on July 1, 1989 and thereafter.

G. A period of three (3) or more years of AOA approved training in diagnostic radiology or radiology shall be required, after the required one (1) year of internship for candidates commencing training prior to July 1, 1989.

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H. A period of three (3) years or more of AOA approved training in radiation oncology shall be required after the required one (1) year of internship.

Section 2. - Application Requirements

A. An application, letters of recommendation and the application fee must be on file with the secretary-treasurer and approved by the credentials committee preceding the next examinational meeting of the Board. All materials submitted by the applicant shall remain the property of the Board.

B. The applicant shall provide letters of recommendation from two (2) diplomates of the Board who are personally acquainted with the applicant and who will vouch for his radiological training and experience, personal character, and who have personally observed the radiological skill of the applicant. The sponsors shall send their letters of recommendation directly to the secretary-treasurer of the Board.

Section 3. - Training Requirements

The candidate shall provide documentary evidence of the required minimum number of years of AOA approved residency training in the specialty for which certification is being sought. This specialty training shall include:

A. Advanced study in the sciences: anatomy, physiology, biochemistry, pathology, pharmacology, radiophysics, radiobiology, and such other basic sciences as are necessary to a

(21)

mature and comprehensive understanding of the prevention, diagnosis, therapy, and management of the disorders involved in radiology.

B. Active experience in the diagnosis and treatment in such amount and diversity that it will assure adequate training in the specialty.

Section 4. - Examinational Requirements

A. Following satisfactory compliance with the prescribed requirements for examination, the applicant is required to pass appropriate examinations planned to evaluate an understanding of the scientific basis of the problems involved in diagnostic radiology or radiation oncology; familiarity with the current advances in diagnostic radiology or radiation oncology; possession of sound judgment; and of a high degree of skill in the diagnosis and therapeutic procedures involved in the practice of diagnostic radiology or radiation oncology.

B. The applicant shall present himself/herself for oral interview when requested to do so by the secretary-treasurer, upon recommendation of the Credentials Committee.

C. The applicant shall appear for oral and written examination at the time and place designated.

D. The applicant is eligible for reexamination after failing all or part of the examination not to exceed two additional examinational sessions within the board eligibility period.

E. Applicants for certification in radiation oncology shall be examined in:

1. Radiobiology
2. Radiophysics and protection
3. Diagnosis of neoplasms
4. Roentgen therapeutics
5. Brachytherapy
6. Use of natural and artificial radioactive substances
7. Treatment planning
8. On-site evaluation may be performed at the discretion of the Board

F. Applicants for added qualifications in one of the fields of interest of general radiology shall be examined in:

1. Anatomy and physiology
2. Methods of examination
3. Technique
4. Indications and contraindications
5. Pharmacology of contrast agents, where applicable
6. Radiation safety and protection
7. Elements of normal and abnormal interpretation applicable to the individual field of interest

G. The films and images used in the image interpretation examinations shall cover the entire specialty and/or fields of interest. A sufficient number of films shall be used for each

anatomical division of the body covering both normal and pathological conditions. Grading in this examination is based upon the applicant's approach to the image and his/her final summation. Practical questions may be interjected to evaluate applicant's ability. This examination may be conducted with two (2) examiners for each applicant. At least one of the examiners must be a member of this Board.

Section 3. - Grading Policy

A. Written Examination

1. A candidate must pass the written examination to be permitted to sit for the oral film interpretation examinations.

2. The minimum passing grade on the total overall written examination is 70%.

3. A candidate who passes the overall examination and scores 65% or above on the Physics section will be permitted to sit for the oral film interpretation examinations and will not be required to take the oral examination in Physics.

4. A candidate who passes the overall written examination and scores below 65% on the Physics section will be permitted to sit for the oral film interpretation examinations and will also be required to take the oral Physics examination.

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5. A candidate will have three opportunities to successfully complete the written examination within the period of board eligibility.

B. Oral Film Interpretation and Oral Physics Examinations

1. A candidate must receive a passing score of 70% at each oral film interpretation station to pass the examination.

2. A candidate who passed the overall written examination but scored less than 65% on the written Physics section will be required to take the oral examination in Physics and score a minimum of 70%.

3. A candidate who fails one or two oral film interpretation examinations, excluding Physics, may repeat the failed examinations only.

4. A candidate who fails three or more oral film interpretation examinations, excluding Physics, must repeat the complete oral film interpretation examinations.

5. A candidate will have three opportunities to successfully complete the oral film interpretation examinations within the period of board eligibility.