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NUCLEAR REGULATORY COMMISSION

ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

In the Matter of:

DATE: August 18, 1980 PAGES: 1-151

AT: Bethesda, Maryland

ALDERSON REPORTING

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UNITED STATES NUCLEAR REGULATORY COMMISSION

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Advisory Committee on the Medical Uses of Isotopes

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Versailles II Meeting Room,
Holiday Inn,
Bethesda, Maryland.

Monday, August 18, 1980

The Advisory Committee on the Medical Uses of Isotopes met at 9:05, chaired by Richard Cunningham.

Panel members in attendance: Drs. Collins, DeLand, DeNardo, Goodrich, Griem, Walker, Holman, Webster, Woodbury, Workman, Almond, and Capt. Briner.

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P R O C E E D I N G S

MR. CUNNINGHAM: We will call the meeting to order, please.

Good morning, ladies and gentlemen. I am Richard Cunningham, a member of the Nuclear Regulatory Commission's Staff. On behalf of the NRC, I would like to welcome each of you to this meeting of the Advisory Committee on the Medical Uses of Isotopes.

The function of the committee is to provide advice to the NRC Staff with respect to the development of standards and criteria to ensure the protection of the public health and safety.

The committee provides expert guidance in formulating rules for the regulation and use of radioisotopes in medical research, diagnosis, and therapy.

This meeting is open to the public in accordance with Public Law 92-463. Advance notice of the meeting was published in the Federal Register on June 25, 1980.

Let the record show that this meeting is being conducted as announced on August 18, 1980, and that the time is 9:10 a.m.

I will chair the meeting in accordance with the format described in the Federal Register meeting notice.

The major purpose of the meeting is to obtain advice for the NRC Staff concerning policy matters, rule changes under

consideration, and things of that nature.

Time has been set aside to hear written and oral statements from members of the public. Those desiring to make written or oral statements were instructed in the Federal Register to notify us prior to the start of the meeting. For those who have not submitted such notification, we will try, if at all possible, to accommodate you, if you do wish to make statements.

For those of you who have submitted statements for the record -- and, incidentally, the transcript of this meeting will be prepared. It will be available in the Public Document Room. -- statements submitted by persons will be attached to the record, and for those who wish to make oral statements, I would ask that you either summarize your written statement or limit your oral statement to no more than five minutes.

The purpose for this, of course, is to allow everybody an opportunity to make statements, if they so choose.

We have a rather full agenda today, and in order to be sure that we cover the full agenda, I am empowered, of course, to restrict additional comments from the public. However, I would like to keep this meeting as open as is possible.

In the past we have had rather full participation from the audience making comments on agenda items and stating positions. I would like to be able to follow that format today.

However, due to time considerations, it may be necessary to restrict the scheduling.

I think at this time I would like to introduce members of the Medical Advisory Committee. Starting on my right and to your left as you face me, first we have at the end of the table Dr. Vincent Collins from the Houston Institute for Cancer, Therapeutic Radiology.

Next to him, Dr. Frank DeLand, VA Hospital, Lexington, Kentucky.

Dr. Sally DeNardo, University of California at Davis campus.

Dr. Goodrich isn't here yet.

Sitting next to me is Dr. Griem, University of Chicago, Therapeutic Radiology.

On my left is Dr. Bill Walker, a member of the NRC Staff, who heads the section on Medical Licensing.

Next to him, Dr. Leonard Holman from Peter Bent Brigham Hospital.

Next to him, Dr. Ted Webster, Mass. General Hospital.

Followed by Dr. David Woodbury, Wayne County General Hospital.

And Dr. Joseph Workman, Duke University Medical Center.

In addition--these are the members of the Medical Advisory Committee. In addition to the members of the Medical Advisory Committee, we have two consultants, Dr. Peter Almond, M.D. Anderson Hospital, adviser on Medical Physics; CAPT. William

Briner, Duke University Medical Center, who is an adviser in Radiopharmacy.

We do have in the audience here -- I will not have time to introduce all the staff, but I might mention a few. We have Mr. Robert Shiaque, who is head of our Office of Standards Development. Bob, will you stick your hand up, so people will know who you are, if they are interested in standards development?

Sitting next to him is Mr. John Guibert, who joined the Standards staff for Radiological Protection, is Assistant Director in that office.

Mrs. Pat Vacca, who is a member of the Medical Licensing section. At the moment she is acting director of that section, while Bill is off on a different assignment.

Mr. Vanda Miller, who is chief of Materials Licensing Branch.

I think most importantly we have two secretaries from the Staff, Mrs. Marge Anderson, and Miss Amy Lipschitz, who will help you with any travel arrangements, phone calls, or whatever. Marge and Amy, will you identify yourselves, so people know who to look to for assistance.

With that, I would like to turn to the agenda. We have three items on the agenda that we must cover today. The first has to do, and is probably the biggest agenda item, training and experience requirements for the practice of nuclear

medicine, those requirements the NRC will place on applicants for its license.

The next agenda item we intend to cover is cardiac dysfunction, which is iodine, and the final agenda item has to do with rule changes that we have under consideration, particularly with regard to radioactive waste disposal. It was not identified as such on the published agenda. We did publish in the Federal Register that section under "new regulations."

Now with regard to training, which I believe will take up most of our time today, there are four subsections of the training requirements, as I see them:

They are the training and experience criteria for nuclear medicine in general, that is, Groups I through III in the medical licensing groups. Then the training and experience criteria for selected nuclear cardiology studies.

The third item we have to cover is the documentation we should ask for as proof of proper or adequate training and experience.

And the fourth thing under the training and experience requirements has to do with acceptance of specialty board certification as evidence of adequate training and experience.

I would like, in order to keep the record as simple as possible, so that we can extract out of the record our various positions, to not mix these various subtopics in training together, to the extent we can, although there is a lot

of overlap in these issues. But I would like, if possible, to take these one at a time.

Now the first issue, I believe, should be general training and experience requirements. I think from this issue other agenda items will begin to fall into place.

At this time, before the committee starts its deliberation on the agenda items themselves, we do have requests to speak on these various topics. I think all requests to speak have to do with training and experience requirements. The organizations that have made requests to speak are, very briefly, as follows:

The American College of Cardiology; the American Osteopathic College of ~~Radiology~~ Radiology; the American Board of Nuclear Medicine; the American College of Radiology; Society of Nuclear Medicine; American College of Nuclear Physicians; and a group of physicians that are currently undergoing some training.

Now, if there are any other persons, as represented groups or as represented individuals, who want to make a statement on the training and experience requirements, I suggest that you get in touch with Mrs. ~~Vodka~~ Vacca, and then she will put you on the list.

Now, as I said, we have these groups listed in the order in which we received requests to make statements. It isn't clear to me whether you would want to make a statement at

the beginning of the deliberation of any of the agenda items, or whether you would want to make your statement as the agenda item comes up, one of the four subitems under training and experience.

I believe that certainly from what I have seen of what has been submitted, the American College of Cardiology, American Board of Nuclear Medicine, Society of Nuclear Medicine, the American College of Nuclear Physicians, as well as the group of physicians who are in training, are going to speak on the general subject of training and experience criteria.

With that as a background, then, I will call upon each group that wants to make a statement, and if you prefer to wait until the specific subject which you are addressing comes up, why, we can come back to you.

First on my list is the American College of Cardiology.

If you make statements, I again remind you that you should limit your oral statement to no more than five minutes. Your complete written statement will be included in the record. You will be asked questions by members of the Advisory Committee after you make your statement, and then questions, perhaps, from members of the audience.

I believe Mr. Coughlan from the American College of Cardiology is first.

As you come up to speak, will you identify yourself and the organization which you represent, so we have that clearly in the record.

DR. COUGHLAN: Thank you, Mr. Chairman. My name is William Coughlan. I am testifying on behalf of the American College of Cardiology, in place of Dr. Zaret, a member of our committee who was to testify. I am going to present his testimony. He was unable to be here.

With me to answer any specific questions, after I give the formal brief statement, is Dr. Jeffrey Borer, whom I also will identify.

You will have this before you, so you can follow.

As you see, Dr. Zaret is Chief of Cardiology at the Yale University School of Medicine, Associate Professor of Medicine & Diagnostic Radiology, Diplomate of the American Board of Internal Medicine, and the Sub-Specialty Board in Cardiovascular Disease.

He had been involved and has been involved in development and application of nuclear cardiology for the past 10 years, and he speaks as a representative of our college, which represents 10,000 physicians and scientists who specialize in heart disease and allied disorders.

The college clearly recognizes the importance of establishing appropriate guidelines for licensure of physicians involved in the performance of nuclear cardiology procedures. The American College of Cardiology addressed the Advisory Committee on December 14th, 1978 concerning this very issue.

Dr. Zaret represented the American College of

Cardiology, again speaking before this Advisory Committee on January 18th, 1980. At that time the position of the college was that a final decision on the training and experience criteria for diagnostic studies limited to nuclear cardiology should be deferred until the reports of two multidisciplinary committees which had been formed by the American Heart Association and the American College of Cardiology had an opportunity to deliberate and make recommendations.

The Committee on Nuclear Cardiology of the American College of Cardiology met on March 20th, 1980 to discuss this topic. Dr. Zaret's statements represent the views of this committee.

At the outset, several important points should be stressed. It is the firm belief of our committee that nuclear cardiology procedures are best performed as a collaborative effort between the cardiologist and nuclear physician.

In individual instances where one physician has been amply trained in both disciplines, this activity can be administered by one person.

However, in most instances, the collaborative input of physicians representing both disciplines is mandatory for appropriate performance and interpretation of these complex procedures.

It should also be emphasized that these recommendations set forth by this committee represent minimal standards

for training and experience necessary for licensure.

We recognize fully that the various medical boards and professional organizations bear an extensive responsibility for establishing appropriate and desirable professional standards and training program requirements.

The general view of the American College of Cardiology concerning the training and experience criteria for isotope licensure for diagnostic studies limited to nuclear cardiology is as follows:

No. 1, training in basic science and radioisotope handling techniques should continue to consist of 200 hours as is currently stated in the NRC training and experience criteria. This should be apportioned as follows:

(1) Radiation physics and instrumentation, 100 hours.

(2) Radiation protection, 30 hours.

(3) Mathematics pertaining to the use and measurement of radioactivity, 20 hours.

(4) Radiation biology, 20 hours: and

(5) Radiopharmaceutical chemistry, 30 hours.

This training in basis science will consist of a confluence of lectures, laboratory sessions, discussion groups, and supervised experience in the laboratory.

No. 2, the total training period, including that time devoted to basic science, should encompass a six-month

period. Within this context, comprehensive clinical exposure in the spectrum of nuclear cardiology procedures should be provided. Since nuclear cardiology is the most technically difficult of the procedures performed in nuclear medicine, we believe that six months is the minimum period in which its various components, including instrumentation, radiochemistry, radiation protection, radionuclide handling and administration, as well as the clinical aspects of the field, can be synthesized and integrated so as to result in acceptable training.

3, the certification for competency should be provided by the program director, who will be the preceptor and the holder of a valid isotope license.

In view of the development and application of nuclear cardiology techniques, our college appreciates being afforded the opportunity to address these important issues. If we can provide you with any further information -- and that might be provided by Dr. Borer, who is with me, I would like to identify him. He is Chief of Cardiac Catherization and Co-Director of Nuclear Cardiology of the New York Hospital, Cornell Medical Center, and Associate Professor of Medicine at Cornell Medical College.

Dr. Borer is also a Diplomate of the American Board of Internal Medicine, and the Sub-Specialty Board in Cardiovascular Disease, and he would be glad to respond to any more technical questions of your committee.

MR. CUNNINGHAM: Dr. Borer, are you going to make any additional statement, or --

DR. BORER: I would be happy to answer any questions you have, sir. I have some comments that I can make, if there are no questions.

MR. CUNNINGHAM: Well, all right, just a moment. I will ask the committee if they have questions of you, and then you can make your comments as you wish.

I would remind the committee that as we proceed here with the various groups making presentations, to bear in mind that if we are going to change our training and experience requirements in both the basic sciences and clinical requirements, that we should do so with ample justification.

So, when you ask questions as you deliberate this matter, please bear in mind that if these requirements are going to change, we have to have clear justification for changing them.

With that statement, I would ask if any members of the committee have questions of Dr. Borer.

Dr. DeLand?

DR. DE LAND: What is the position of the American College of Cardiology with respect to the third statement, as it also refers back to the second statement? Are you proposing that the NRC provide competency and diagnostic or clinical diagnostic nuclear angiocardiology, or that they are purely to

provide competency in the handling of materials and the patients and instrumentation, and so forth, in the clinical studies?

DR. BORER: The latter, Dr. DeLand. We are proposing that the NRC provide certification of the competence of a given physician to handle the isotopes, and to perform procedures safely.

We are not suggesting that the NRC in any way determine the competence of the individuals in interpreting the results of their tests.

MR. CUNNINGHAM: Dr. Workman?

DR. WORKMAN: Under part 2, the total training period is a six-month period. The next sentence within this context, comprehensive clinical exposure in the spectrum of nuclear cardiology procedures should be provided, do you have any -- do you want to expand on that at all?

DR. BORER: The time that we believe that is appropriate for such training is based on several considerations. First of all, in my experience in nuclear cardiology, which now spans seven years, and that of other members of the committee of the American College of Cardiology, we believe that six months' time and 500 hours of clinical experience is an absolute minimum requirement to permit the safe and adequate handling of isotopes in performance of the techniques involved in nuclear cardiology.

The American College of Cardiology and myself

personally believe that actually 12 months might generally prove more appropriate than six months, but in deference to the realistic needs of practitioners who say their training already is completed, we believe that minimum acceptable competence can be reasonably assured by six months of experience, as outlined in Dr. Zaret's testimony.

In support of this recommendation, I point out first that nuclear cardiology procedures are the most complex again of all nuclear medicine procedures, as they involve use of a computer, and the need for the long period of training is necessitated in large part by the need for experience in performing computer manipulations in a manner likely to result in clinically beneficial results.

In our views, only if such interpretable and potentially clinically usable results are achieved is it permissible for the individual to inject isotopes into a human subject.

I point out, also, regarding the similarity in all recommendations for basic science training, that those suggested for basic science training preparatory to broad licensing by the Society of Nuclear Medicine and other societies.

First, the American College of Cardiology's suggestions antedated those formulated by other societies, and were not formulated in response to them. I can't, therefore, comment on or take responsibility for the subsequent formulations of other societies, but more importantly, the 200-hour training

requirement set by the Nuclear Regulatory Commission in 1976-77 actually preceded the development and widespread clinical application of nuclear cardiology techniques, and particularly of computer-based radionuclides to the angiography and computer-based values for scintigraphy.

Therefore, the Nuclear Regulatory Commission could not consider the need for training mandated by the availablity of these procedures.

Finally, it is important to remember that the basic principles taught during the period of training are the same for all isotopes, so that it would be reasonable that the number of hours required for broad licensing and for limited handling licensing might be similar.

The differences in the procedures are primarily those of application, which are learned during the clinical training, and that relates to our recommendation for the length during that period.

MR. CUNNINGHAM: Any more questions of Dr. Borer?

Dr. Webster?

DR. WEBSTER: I am exercised by the implication that the total training period very often for nuclear cardiologists within in fact six months -- the six months you are asking for in this submission, and that, of course, is identical to what you are also asking for a license from the Nuclear Regulatory Commission.

Could you justify the six months for the total clinic training to establish clinical competency to be the same time as is necessary for the NRC license, which is largely devoted to safety concepts?

DR. BORER: Dr. Webster, let me clarify that point. I am not suggesting that clinical competence is achieved within six months. I don't think that it is. I think that, in fact, clinical competence requires far longer training.

I am suggesting only that in order for procedures to be performed in an adequate fashion so that they are likely to be interpretable and, therefore, to justify whatever risk are involved in injection of an isotope into a patient, that six months is required.

My position and that of the American College of Cardiology is that six months of training is required for safety and handling of the procedures and competence in performance of the techniques involved with the injection of the isotope and the obtaining of data.

Clinical competence would involve the interpretation of data which I believe would require a longer period of experience.

DR. WEBSTER: Can I follow up on that?

MR. CUNNINGHAM: Certainly.

DR. WEBSTER: What concerns me is, is there anything in the pipeline, so to speak, on the part of the professional

organizations in cardiology to demand, let's say, one year of training to establish the clinical competency?

DR. BORER: Those problems regarding the certification of clinical competence are now being discussed actively by the appropriate committees of the American College of Cardiology, and I believe the American Heart Association as well. Certainly the American College of Cardiology is attempting to deal with this problem right now.

As yet, no recommendations, no formal recommendations have been made.

MR. COUGHLAN: If I may add just one point.

MR. CUNNINGHAM: Mr. Coughlan.

MR. COUGHLAN: At the meeting of the college in April, the committee did discuss these training requirements, more specific training requirements for the cardiologists who need at least six months of nuclear medicine training. So it is an active item of consideration of our committee, which probably will be meeting again within the next six months.

MR. CUNNINGHAM: Any more questions?

Dr. Workman?

DR. WORKMAN: If I understand you, then what you are suggesting is that anyone who really completes the six months training is competent in clinical cardiology -- is competent in cardiac nuclear medicine?

DR. BORER: No. What I'm suggesting is that anyone

who completes the six months' training is competent to perform a procedure which then has a high probability of being interpretable by somebody with clinical competence, so the clinical benefit to the patient can result.

MR. CUNNINGHAM: Any more questions?

Thank you very much, Dr. Borer.

(The statement follows:)

(1)

Presentation of
Barry L. Zaret, M.D., F.A.C.C.
on behalf of
The American College of Cardiology

Before the Advisory Committee
on the Medical Uses of Isotopes
of the United States Nuclear
Regulatory Commission

August 18, 1980
Bethesda, Maryland
(Read by William D. Coughlan
Deputy Executive Director
in absence of Dr. Zaret)

My name is Barry L. Zaret. I am Chief of Cardiology at Yale University School of Medicine, Associate Professor of Medicine & Diagnostic Radiology, Diplomate of the American Board of Internal Medicine and the Sub-specialty Board in Cardiovascular Disease. I have been involved in the development and application of Nuclear Cardiology for the past ten years. I am speaking as a representative of The American College of Cardiology which is a professional medical specialty organization of more than 10,000 physicians and scientists who specialize in heart disease and allied disorders.

The College clearly recognizes the importance of establishing appropriate guidelines for licensure of physicians involved in the performance of nuclear cardiology procedures. The American College of Cardiology addressed the Advisory Committee on the Medical Uses of Isotopes on December 14, 1978 concerning this very issue. I represented The American College of Cardiology, again speaking before this advisory committee, on January 18, 1980. At that time the position of The American College of Cardiology was that a final decision on the training and experience criteria for diagnostic studies limited to nuclear cardiology should be deferred until the reports of two multidisciplinary committees which had been formed by the American Heart Association and American College of Cardiology had an opportunity to deliberate and make recommendations. The Committee on Nuclear Cardiology of the American College of Cardiology met on March 20, 1980 to

discuss this topic. My statements represent the views of this committee.

At the outset, several important points should be stressed. It is the firm belief of our committee that nuclear cardiology procedures are best performed as a collaborative effort between the cardiologist and nuclear physician. In individual instances where one physician has been amply trained in both disciplines this activity can be administered by one person. However, in most instances, the collaborative input of physicians representing both disciplines is mandatory for appropriate performance and interpretation of these complex procedures. It should also be emphasized that the recommendations set forth by this committee represent minimal standards for training and experience necessary for licensure. We recognize fully that the various medical boards and professional organizations bear an extensive responsibility for establishing appropriate and desirable professional standards and training program requirements.

The general view of The American College of Cardiology concerning the training and experience criteria for isotope licensure for diagnostic studies limited to nuclear cardiology is as follows:

(1) Training in basic science and radioisotope handling techniques should continue to consist of 200 hours as is currently stated in the NRC training and experience criteria. This should be apportioned as follows: (1) Radiation physics and instrumentation (100 hours); (2) Radiation protection (30 hours); (3) Mathematics pertaining to the use and measurement of radioactivity

(20 hours); (4) Radiation biology (20 hours); and (5) Radiopharmaceutical chemistry (30 hours). This training in basic science will consist of a confluence of lectures, laboratory sessions, discussion groups and supervised experience in the laboratory.

(2) The total training period (including that time devoted to basic science) should encompass a six month period. Within this context comprehensive clinical exposure in the spectrum of nuclear cardiology procedures should be provided. Since nuclear cardiology is the most technically difficult of the procedures performed in nuclear medicine, we believe that six months is the minimum period in which its various components, including instrumentation, radiochemistry, radiation protection, radionuclide handling and administration, as well as the clinical aspects of the field can be synthesized and integrated so as to result in acceptable training.

(3) The certification for competency should be provided by the program director who will be the preceptor and the holder of a valid isotope license.

In view of the rapid development and application of nuclear cardiology techniques, The American College of Cardiology appreciates being afforded the opportunity to address those important issues. If I can provide you with any further information I will be glad to do so.

Thank you for your attention.

MR. CUNNINGHAM: The next group that asked to make a statement, if we proceed chronologically, is the American Osteopathic College of Radiology, and I believe their subject, though, has more to do with board certification.

I would ask Dr. Faerber if he wants to make a statement now, or if he would prefer to wait until we reach board certification.

DR. FAERBER: I prefer to wait.

MR. CUNNINGHAM: Okay. Thank you very much, Dr. Faerber.

We will go then to the American Board of Nuclear Medicine, who does want to speak on the general topic of training and experience requirements, as well as board certification. Perhaps the two can be combined.

Dr. William Blahd will represent the American Board of Nuclear Medicine.

Bill.

DR. BLAHD: Thank you, Mr. Cunningham and members of the Advisory Committee.

I am Dr. William Blahd of the American Board of Nuclear Medicine, from Los Angeles, a Professor of Medicine at the UCLA School of Medicine in Los Angeles, and certified by the American Board of Nuclear Medicine and Board of Internal Medicine, and I am engaged in nuclear medicine practice for more than 25 years, past president of the Society of Nuclear Medicine.

I am on the Board of Directors of the Board of Nuclear Medicine.

I am here today representing the American Board of Nuclear Medicine. The board wishes to make a statement concerning the general requirements for licensure of individuals for the use of radioactive materials in humans, supplementing those presented to you by Dr. Fish on January 18th, 1980.

You have the full statement from the board, and I will only attempt to summarize that statement, and it is going to be brief, Mr. Cunningham.

Because the procedures in nuclear medicine are becoming more complex, and larger doses of materials are being used, and many more patients are being subjected to nuclear medicine procedures, and because of the concern of the medical profession and the public with respect to safety when nuclear medicine or radioactive materials are administered, the American Board would like to recommend the following:

That the Nuclear Regulatory Commission require, as a condition for license for the use of unsealed sources of radioactive material in humans, six months special training and experience, to include a minimum of 200 hours of basic training, which we expect to include such matters as as radiation physics and instrumentation; radiation protection; radiation biology; the use of radiopharmaceuticals; and appropriate mathematics and statistics.

In addition, supervised clinical training and experience in an institutional program accredited by the Liaison Committee on Graduate Medical Education, or equivalent thereto.

In addition, the board requests that the Nuclear Regulatory Commission discontinue the issuance of limited licenses for the use of internally-administered radioactive materials in humans.

The board recommends that the Nuclear Regulatory Commission state specifically that its license for medical use of radioactive materials assures radiation safety, but does not assure and does not certify medical competence of the licensee.

The substance of this statement is in accord with the recommendations of the Federated Council of Nuclear Medicine Organizations. It was adopted by the board of trustees and the Society of Nuclear Medicine on June 23, 1980, and is consistent with Resolution 148 passed by the House Delegates of the American Medical Association in July 1980.

The American Board of Nuclear Medicine requests that these recommendations be adopted by the Nuclear Regulatory Commission forthwith in the interest of public safety, and to ensure the quality of medical care.

Thank you for allowing me to make this statement, Mr. Cunningham. I will have further comments when the matter of therapeutic administration is addressed.

MR. CUNNINGHAM: All right. Thank you very much, Dr.

Blahd.

Questions from members of the committee?

I guess there are no questions at this time, Bill. I'm sure we will come back to you.

(The statement follows:)

(2)

August 4, 1980

Mr. Richard Cunningham, Director
Division of Fuel Cycle and Material Safety
U.S. Nuclear Regulatory Commission
Washington, D. C. 20555

SUBJECT: Additional comments of the American Board of Nuclear Medicine concerning general requirements for licensure of individuals for the use of radioactive materials in humans to supplement those which were presented to the Advisory Committee on January 18, 1980.

Dear Mr. Cunningham:

Enclosed is a statement made on behalf of the American Board of Nuclear Medicine concerning general requirements for licensure of individuals for the use of radioactive materials in humans to supplement those which were presented to the Advisory Committee on January 18, 1980. The substance of this statement was considered at great length by the Federated Council of Nuclear Medicine Organizations, and was adopted by the Society of Nuclear Medicine at its Board of Trustees meeting held June 23, 1980. This statement is also consistent with a resolution (No. 148) that was passed by the House of Delegated of the American Medical Associated at its July 19-24, 1980 meeting.

This current statement is also in concert with the ABNM statement of January 18, 1980 as both recommend a minimum of six months of special education, training and experience. The current statement is somewhat more flexible in recommending a minimum of 200 hours of basic science topics allowing for a variable and necessary period of supervized application of basic science principles throughout most of the six months training experience. The current statement also attempts to address the problem of quality and credibility of the training program and experience of the potential radioactive materials user. It is hoped that this material will be distributed to the members of the Advisory Committee for their use at their August 18, 1980 meeting.

I unfortunately will be unable to attend the August 18. 1980 meeting as originally planned. Accordingly, Dr. William Blahd, Chairman of the Credentials Committee, American Board of Nuclear Medicine will present to the Advisory Committee this material as well as the statement concerning licensure for administration of radionuclides to humans for therapeutic purposes previously sent to you by Dr. Joseph F. Ross.

The entire Medical community is most appreciative of your concern and consideration of these matters.

Sincerely,

Mathews B. Fish, M.D.
Chairman

Enclos:

MBF:mlh

STATEMENT MADE ON BEHALF OF

THE AMERICAN BOARD OF NUCLEAR MEDICINE

CONCERNING

GENERAL REQUIREMENTS FOR LICENSURE OF INDIVIDUALS FOR THE USE OF RADIOACTIVE MATERIALS IN HUMANS TO SUPPLEMENT THOSE WHICH WERE PRESENTED ON JANUARY 18, 1980

BEFORE

THE NUCLEAR REGULATORY COMMISSION'S ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

AUGUST 18, 1980

August 4, 1980

THE AMERICAN BOARD OF NUCLEAR MEDICINE RECOMMENDS:

that the Nuclear Regulatory Commission, in their licensing statement indicate specifically that theirs is a safety license rather than a certification or statement of medical competence.

that the issuance of limited licenses for uses of internally administered radioactive materials (except for sealed sources) in human subjects in selected organs or systems be discontinued.

that the issuance of licensure by the Nuclear Regulatory Commission for the use of radioactive materials in human subjects requires for all licensees a minimum of six months of special education, training and experience in the use of radioactive materials in human beings.

that the six months of special education, training and experience shall be taken in a training program accredited by the Liaison Committee for Graduate Medical Education or equivalent thereto and shall include as a minimum the following:

a. Training in basic radionuclide handling techniques consisting of lectures, laboratory sessions, discussion groups or supervised experience in these specific areas: (200 hours total)

   (1) Radiation physics and instrumentation (80 hours)

   (2) Radiation protection (20 hours)

   (3) Mathematics, statistics and computer science pertaining to the use and measurement of radioactivity. (40 hours)

   (4) Radiation biology (20 hours)

   (5) Radiopharmaceutical chemistry (40 hours)

   (The hours listed next to each of the five subjects above are suggested values and should not be interpreted as specific requirements)

b. Supervised clinical training and experience in Nuclear Medicine. The clinical training should cover all appropriate types of diagnostic procedures and should include:

(1) Supervised examination of patients to determine the suitability for radionuclide diagnosis and recommendation on dosage to be prescribed.

(2) Collaboration in calibration of the dose and the actual administration of the dose to the patient, including calculation of the radiation dose, related measurement and plotting data.

(3) Supervised interpretation of results of radionuclidic diagnostic procedures and follow up of patients when required.

MR. CUNNINGHAM: The next group is the American College Radiology, represented by Dr. James Christie. It isn't clear whether you want to make a statement or not, Jim. Do you want to make a statement?

DR. CHRISTIE: Not at this time.

MR. CUNNINGHAM: All right.

Next we have the Society of Nuclear Medicine, represented by Dr. Paul Hoffer. Dr. Hoffer?

DR. HOFFER: Mr. Cunningham, members of the committee, my name is Paul Hoffer. I am the vice president of the Society of Nuclear Medicine, and I am speaking on behalf of the Society of Nuclear Medicine.

I think the Society of Nuclear Medicine, as most of you know, I think, is the largest organization representing the largest number of practitioners and allied scientists and technologists in the field of nuclear medicine.

I have already submitted a statement, a written statement, and I will not reiterate all of the information that is contained in that statement, other than to summarize it by saying that the Society of Nuclear Medicine wishes to go on record as supporting the position of the Federated Council of Nuclear Medicine Organizations and its recommendation to this Advisory Committee; that the Society supports this primarily because it feels that there is a desperate need to extend the overall training requirement in nuclear medicine for licensing;

that the current licensing requirement of three months is woefully inadequate; and while the Society has some concerns that six months may not be ideal, and perhaps it should be extended longer than that, that at least six months would represent a significant improvement over the current situation.

Furthermore, the Society makes its recommendation that the training in nuclear medicine be done in approved training programs, and tries to emphasize through those programs that any actions by this group should be taken as a licensing action, and not as a recommendation to the directors of training programs who design their programs specifically around the licensing requirements.

And furthermore, the Society wishes to emphasize that the Nuclear Regulatory Commission in its licensing statements indicate specifically that theirs is a safety license rather than a statement of medical competence.

I would be happy to answer any questions that any members of the committee may have.

MR. CUNNINGHAM: Thank you very much, Dr. Hoffer.

One question: As I recall, you said the six months' training requirement is probably not even enough for licensure. You also recognize that our primary emphasis for purposes of NRC licensing is not quality so much as it is assuring the issue of safety for all involved, for the physician and the patient.

Now do I understand you correctly, when you said that six months' training is not enough to attain sufficient training to ensure radiation safety?

DR. HOFFER: There is a great philoscphical problem here, and that problem is that the policeman frequently defines the law, and with regard to determining the length of training, I think there is a general feeling amongst all physicians, or at least amongst most physicians, that it is desirable to have a full year of training in the field of nuclear medicine before practicing any aspect of nuclear medicine.

The question comes up as to what represents an acceptable minimum with regard to safety, and because the standard of practice is in a very intimate way related to the safety of practice, that is to say if one injects a radionuclide into a patient and performs an examination, and then does not do an adequate job of interpreting that examination, you can make the argument that that was in essence a radiation dose that was given to the patient that did not represent something that worked to the patient's benefit.

This is a very, very difficult philosophical question, and I am not sure that everybody has come to grips exactly with an adequate answer to that question, and the only thing that we could decide on as a group was that the current three months was definitely inadequate from the safety point of view; that six months would be definitely preferable.

This appeared to be a consensus of many organizations involved in the practice of nuclear medicine, and we were willing to go along with the six-months recommendation to extend the three months, rather than get into a further hassle with regard to whether one year is necessary or not.

MR. CUNNINGHAM: Well, then, what you say worries me somewhat, because there are people that are running these training courses, as you well know, people in training, people who have just received training in a three-month course. If we change this to six months now, it is not a light step to take because it has broad impact throughout the training community.

Now the way you phrase this worries me a little bit, because if we should move to a six-month training requirement, are we then going to be faced immediately with what that training requirement is and deliberate that issue?

DR. HOFFER: That is a definite possibility, and the only protection that is built into this is it was the feeling of the Society of Nuclear Medicine that the program directors should have significant influence over determining what is a necessary program, and just so long as all of the training were provided within the context of approved programs, that the program directors would be very reluctant to have six-month training programs if they felt it was in the best interest of both safety and medical practice, that these programs should be a year in length. And we recognize the problems associated

with trying to establish regulations in a field where obviously there has been very significant progress, both in specific areas and in also the overall breadth of the field over the course of the last five years, 10 years, actually.

The history of nuclear medicine has been one of tremendous expansion and growth. And so we feel for you in terms of trying to establish licensing regulations in this regard, and we are concerned ourselves that people who practice nuclear medicine and who receive radionuclides are competent in terms of providing for the safety of their patients.

The only way we could see to do this at this point was to go along with the consensus of other organizations that this requirement be extended to six months, and then specify that we hoped that you would also specify that this be done within the context of an approved training program, with the understanding that the directors of that program would themselves act as a protective mechanism and ensure that they did not run an inadequate program with regard to the length or type of training within the program.

MR. CUNNINGHAM: Members of the committee? Dr. Webster?

DR. WEBSTER: I have three questions. The first one is in the Federated Council of Nuclear Medicine, there did not seem to be any representation from the interns from the American College of Physicians, and I wondered why that was.

And I am particularly asking that question in the context of your move to eliminate the limited license which would impact upon people in the endocrine area, particularly people doing thyroid work.

The second question --

DR. HOFFER: Can I answer them one at a time? With regard to the Federated Council, although I am a member of that organization, I am not speaking for that organization, and I would prefer not to speak for that organization, and therefore I can't legitimately answer your question.

If there is a representative here to specifically represent the Federated Council, I would prefer that they answer that question.

DR. WEBSTER: I have another question.

MR. CUNNINGHAM: Maybe Bill Briner wants to say something on that point.

CAPT. BRINER: In regard to a representative of the American College of Physicians, it can be answered quite simply: They are not a member of the Federated Council.

DR. WEBSTER: That disturbs me, because the American Board of Nuclear Medicine is a tripod organization, which has one-third input, as I understand it, from the internists, and therefore they obviously have a legitimate position, or should have a legitimate position in making -- coming to these kinds of conclusions.

DR. HOFFER: I would only say that on the part of the Society of Nuclear Medicine, we concurred in that organization's recommendation. Whether that organization's representation was based on a total consensus of all organizations, or whether one or more organizations were not part of that consensus, I cannot say.

DR. WEBSTER: The second question is rather similar. It really relates to this issue of the limited license. Whether in your opinion anybody who is using radionuclides clinically needs to have just six months of training, which is a rather drastic increase in the present situation, as regards the Nuclear Regulatory Commission, who are requiring for, let's say, Groups IV and V which are therapeutic uses of sources, only 80 hours of basic scientific training as against 200 hours for the people using radioactive materials diagnostically, and also requires a rather limited number of clinical cases in order to qualify for a license.

There is a much greater difference between your position with regard to Groups IV and V, I would say, than the difference that you are according for the diagnostic groups.

DR. HOFFER: This issue I can't speak on. It is the feeling of the Society of Nuclear Medicine that six months is a minimum safety requirement. There is a consensus within the organization. That is not to say it is not possible for an individual who practiced some aspect of medicine that involves

the use of radionuclides with less than that amount of training.

I think there are individuals who have less than that amount of training, at a time when the field was not that broad, and who have subsequently become knowledgeable in the field, not by virtue of training, but by virtue of practide, and following the developments within the field.

Secondly, we feel that there is nothing in this statement that prohibits somebody from practicing some specific aspect of nuclear medicine, be it thyroidology, endocrinology, nuclear cardiology, with less training, provided they practice it in conjunction with somebody who is familiar with the safety requirements, and will supervise the handling of the radionuclides.

So that it is not as if we would wish that you would prohibit the person who had two or three months training in interpretation of liver scans from ever interpreting a liver scan; but rather you would set a licensing requirement that would say that somebody in that group of people would supervise the handling of the radionuclide, so that even though that person might not be the person that interpreted or did the medical interpretative aspect of all those examinations, that there was somebody in the group who had six months' familiarity which we feel is a minimum safety requirement.

DR. WEBSTER: Well, I'm really concerned that you are departing from the idea of the broad practice of nuclear

medicine, and you are reaching down into this limited practice, and you are imposing or trying to impose some conditions for those people.

What about the radiation safety officer? Maybe he can supervise the safety aspects. Does it require this heavy sort of clinical intervention which you are now proposing?

DR. HOFFER: I think in those institutions with broad licenses, it may be the radiation safety officer who may be the person who is intimately involved in that particular aspect, but I think that no regulation will be perfect, and any regulation that you hit upon will, on the one hand, wind up preventing somebody who is, by virtue of some bizarre nature of their training, qualified just by the fact that they do not meet the formal qualifications.

By the same token, there is going to be somebody with six months training who is not competent, may not be competent. I think that is unavoidable. I think what you are essentially trying to do is to do what's best for the greatest number, with the least injury to the population, or to the individuals practicing in the field. And I think that that is the basis under which the Society of Nuclear Medicine has made its recommendation.

DR. WEBSTER: One last question. The third question relates to your use of the phrase several times "woefully inadequate" with regard to the three months. I have not seen

any defense of that statement. Can you really point to any facts indicating that the three months presently required training for Groups I, II and III are inadequate?

And let me put that into context on the fact that the majority of diagnostic imaging now in the country is accomplished by radiologists who have got only three months' training. Are you saying that they are not competent?

DR. HOFFER: What I am saying is as of two years ago, I think that requirement and that length of training with regard to the safe use of radionuclides was reasonable. But at the moment, at this point in time, with the developments that have occurred over the last two or three years, it was the consensus of the Society of Nuclear Medicine that that amount of training is woefully inadequate, and I think in essence what has happened is in particular with regard to nuclear cardiology there has been such tremendous growth in the field that it is now impossible to train people to the point of safe handling of radionuclides with three months of training.

That is not to cast aspersion on any previous actions of this group. It is rather to express the tremendous growth that has occurred within the field of nuclear medicine within a short period of time, with a history of growth dating way back.

DR. WEBSTER: Thank you.

MR. CUNNINGHAM: Dr. Collins?

DR. COLLINS: A little while ago you referred to

radiation dose. Should I prescribe the treatment of a carcinoma of the lung or cervix, as six months of treatment? The result would be somewhat unpredictable and not duplicable.

Here we are talking only of the temporal element of the training that is necessary. Now there was a time in radiotherapy when we were content to prescribe milligram-hours and to consider the result a desirable result.

We are far beyond that. Now until we get beyond limiting the requirements to 200 hours, six months, a year, I think we are back in the primitive stage of prescribing doses in milligram-hours.

Now, granted, that's where we are at this moment, but I don't think we should consider it satisfactory. What are your suggestions for going beyond that primitive stage?

DR. HOFFER: I can only say that there are two aspects of radiation dose and to training, the quantity and the quality. And with regard to the quality of training, I think that it is almost impossible to establish by regulation.

The professional organizations themselves have attempted to do this, and I think by and large have done a very reasonable job, and I think that just so long as the training in this area is performed within the context of approved training programs in either nuclear medicine or nuclear radiology, and frequently those programs are concurrent, that that is the one protection that one would have on the quality of the program.

And that with regard to licensing requirement for practical purposes, the only thing one can do is establish the quantity and hope that the quality is adequate.

DR. COLLINS: I don't think that's a satisfactory answer, any more than my just saying go back and treat a patient for six weeks.

MR. CUNNINGHAM: Any other questions of Dr. Hoffer?

I'm sure we'll come back to you, Dr. Hoffer. Thank you very much.

(The statement follows:)

(3)

THE SOCIETY OF NUCLEAR MEDICINE

July 31, 1980

Richard Cunningham
Nuclear Regulatory Commission
Washington, D.C. 20555

Re: Advisory Committee on the Medical Uses of Isotopes: Public Meeting August 18, 1980

Dear Mr. Cunningham:

I will be atending the Public Meeting and wish to speak on benalf of the Society of Nuclear Medicine. The members of the Society, approximately 9,500 in number, represent the largest organized group of individuals involved with the medical use of radionuclides. The organization includes physicians, technologists and other scientists. Its purposes are primarily educational and scientific.

The Society is concerned with the proper training of all individuals who administer and work with radionuclides used in medical facilities. The Society wishes to insure that federal regulations regarding this training are adequate. The Society also wishes to insure that decisions relating to medical competence not be assumed by any federal agency or licensing process.

To these aims, the Board of Trustees of the Society passed the following resolution at its meeting on June 23, 1980:

Resolved, That the Society supports the compromise proposal (see below) of the Federated Council of Nuclear Medicine Organizations consisting of the Society of Nuclear Medicine, the American College of Nuclear Physicians, the American College of Nuclear Medicine, the American College of Radiology, the College of American Pathologists and the American Board of Nuclear Medicine regarding minimum licensing requirements as an interim position. We support this primarily because it extends (i.e. increases) the current three month requirement which we feel is woefully inadequate and be it further

Resolved, That the Society strongly recommends that Program Training Directors design their programs based primarily on the training needs as they perceive them, rather than based primarily on a specific minimum licensing requirement of the Nuclear Regulatory Commission and, be it further

Resolved, That we recomend that the NRC, in their licensing statements indicate specifically that theirs is a safety license rather than a statement of medical competence.

Compromise Proposal of the Federated Council of Nuclear Medicine Organizations

Resolved, That the issuance of limited licenses for uses of internally administered radioactive materials (except for sealed sources) in human subjects in selected organs or systems be discontinued.

Resolved, That the issuance of licensure by the Nuclear Regulatory Commission for the use of radioactive materials in human subjects requires for all licensees a minimum of six months of special education, training and experience in the use of radioactive materials in human beings.

Resolved, That the six months of special education, training and experience in a training program accredited by the LCGME shall include as a minimum the following:

General Training

a. Training in basic radionuclide handling techniques consisting of lectures, laboratory sessions, discussion groups or supervised experience in these specific areas: (200 hours total)

   (1) Radiation physics and instrumentation (80 hours)

   (2) Radiation protection (20 hours)

   (3) Mathematics, statistics and computer science pertaining to the use and measurement of radioactivity (40 hours)

   (4) Radiation biology (20 hours)

   (5) Radiopharmaceutical chemistry (40 hours)

   (The hours listed next to each of the five subjects above are suggested values and should not be interpreted as specific requirements)

b. Supervised clinical training and experience in Nuclear Medicine. The clinical training should cover all appropriate types of diagnostic procedures and should include:
   (1) Supervised examination of patients to determine the suitability for radionuclide diagnosis and recommendation on dosage to be prescribed.

(2) Collaboration in calibration of the dose and the actual administration of the dose to the patient, including calculation of the radiation dose, related measurement and plotting data.
(3) Supervised interpretation of results of radionuclidic diagnostic procedures and follow up of patients when required.
(4) Study and discussion with preceptor of case histories to establish most appropriate diagnostic procedures, limitation, contraindication, etc.

I wish to have this statement included as a part of the record of the Public Meeting and be given due consideration by the Advisory Committee.

Respectfully Submitted,

Paul B. Hoffer, M.D.
Vice President
Society of Nuclear Medicine

PBH/rac

MR. CUNNINGHAM: The next group that requested to speak on the subject was the American College of Nuclear Physicians. I believe they are represented by Mr. McBain. Is Mr. McBain here?

MR. MC BAIN: I am Jim McBain, Executive Director of the American College of Nuclear Physicians, representing over 1100 physicians active in the practice of nuclear medicine.

This issue, as you can well tell, has generated much concern among nuclear physicians, and one of the concerns is that the current NRC training-experience criteria are inadequate.

Again, going back to the inadequate discussions.

We are well aware that there have been dramatic increases in the medical uses of radioiosotopes, increases in the number of nuclear physicians and patients, and our concern is that these studies are done with a dose low enough to be safe, and yet adequate for good diagnosis.

We are also concerned with public safety, and to the handling of radioisotopes, and also the disposal of low-level radioactive materials.

It is our opinion that, rather that since we feel that these training criteria are already low, that rather than look into the lessening of criteria, that the NRC should look into increasing them.

Specifically, basic nuclear medicine sciences, about 480 hours.

Nuclear medicine physics, 80 hours.

Radiation biology, 40 hours.

Radiation safety and health physics, 40 hours.

Radiopharmaceutical science, 80 hours.

Relevant basic medical sciences, 80 hours.

Mathematics, statistics, and computer sciences, 80 hours.

Nuclear medical instrumentation, 80 hours.

All this need not be didactic, but it could be in seminars, et cetera, in addition to another 480 hours of clinical training.

To the issue of reduction in training for limited license, the college, as we said in January, no change. Go back to the practice of limited licenses. We feel that cardiovascular medical procedures are the most complex in the practice of nuclear medicine, and since we feel that the training and experience criteria are already inadequate for the general license, there is no reason for the NRC to reduce them for the most complex aspect of practice.

MR. CUNNINGHAM: Thank you very much, Mr. McBain.

The question I have involves the previous question of Dr. Webster. You call for an increase of training, a substantial increase, and you base this, I gather from your statement, on a concern for the public health and safety of the public in handling radioactive materials.

Do you have something to say which would indicate that the current training requirements are not enough for the safe handling of radioactive macerials, including waste disposal?

MR. MC BAIN: I think in petitioning for a change, one of the preambles to an NTC petition is that changed situations of fact or law give you the right to petition.

I think it is the consensus among our physicians that because of the increase of the practice of nuclear medicine, increases in physicians, radiopharmaceuticals, and the patients receiving them, that the previous safety requirements are inadequate today, and that because of that changed situation, we are suggesting that you increase the safety requirements to today's needs.

And even though these requests are markedly higher than the current license, we still feel it is only basic for safety.

MR. CUNNINGHAM: I guess I have a little bit of trouble with the logic of saying that just because the size of the field is increasing, we should increase training requirements.

MR. MC BAIN: There is more to it than size. I think there is more complexity in procedures.

MR. CUNNINGHAM: Dr. Holman?

DR. HOLMAN: I am curious about that point, and I wonder if you could expand on that. One comparison that would be useful is, according to your guideline, the number of hours

required for the safe handling of the isotope now exceeds the number of hours required to achieve a doctorate in nuclear engineering at MIT, and I wonder how you can justify in terms of safety, when we compare those aspects, nuclear engineering and licensure.

MR. MC BAIN: What section is that?

DR. HOLMAN: 480 hours, plus 480 hours of clinical training.

MR. MC BAIN: That's about six months. My answer to that is that it is the consensus feeling of the physicians we have talked to on this issue that this is necessary. Whether perhaps the other requirements should be upgraded, too, it is the consensus of our physicians that this be -- your current licens requirements are inadequate, and they should be upgraded to provide adequate safety.

DR. WALKER: Let me just clarify one thin . I think it might be a misunderstanding here. In our current requirements, we discussed contact hours versus credit type hours and hours of this type. And, Mr. McBain, if I am correct, you are talking about contact hours here, rather than just maybe -- Dr. Holman was talking about credit hours.

MR. CUNNINGHAM: Dr. Webster?

DR. WEBSTER: I am exercised by your reaching out to the waste disposal problem as being a justification for more clinical training, which is what we are really coming down

to. You are not asking for more basic science training; you are not asking that the 30 hours in radiation safety be increased to some other larger number.

It seems to me that a physician really has very little to do with radiation safety, with the waste disposal problem. In most instances that I am familiar with, this is done by different individuals, and the physician feeds into that individual, namely the radiation safety officer. And I can't credit that one of your arguments for more training can relate to the waste disposal problem.

MR. MC BAIN: You are right. Maybe the physician doesn't get directly involved in the waste disposal problem, or at least he hasn't, but the impetus today is that they are. The questions are always, do you need to have physicians in waste disposal, and how does it affect the practice of nuclear medicine?

DR. WEBSTER: The answer to that, particularly with a technician, is very little.

MR. MC BAIN: Well, without waste disposal, we get into a large issue on waste disposal. But we run into that problem. We think we are going to have a large problem.

MR. CUNNINGHAM: I think there is quite a difference between the broad issue of waste disposal and having waste disposal capacity available for fuel cycle and radiopharmaceutical manufacturers who supply the pharmaceuticals, and the issue of

adequate training of physicians in relation to that waste disposal problem. I think Dr. Webster cannot see that.

Are there any other questions of Mr. McBain?

If not, thank you very much, Mr. McBain. I hope you will be here for the deliberations as they go on.

(The statement follows:)

(4)

STATEMENT OF THE

AMERICAN COLLEGE OF NUCLEAR PHYSICIANS

BEFORE THE

NUCLEAR REGULATORY COMMISSION

ADVISORY COMMITTEE ON THE

MEDICAL USES OF ISOTOPES

AUGUST 18, 1980

I am James McBain, Executive Director of the American College of Nuclear Physicians. The ACNP represents over 1,100 physicians and scientists actively engaged in the practice of nuclear medicine.

One of the issues that has generated much concern and discussion among practitioners of nuclear medicine is that the current NRC training and experience criteria for physician-users of radioactive materials is inadequate.

We are all aware that there have been dramatic increases in the medical uses of radioisotopes, increases in the number of nuclear medicine physicians and other nuclear medicine personnel, as well as increases in the number of patients receiving nuclear medicine studies. The major concern of nuclear

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medicine practitioners is, of course, that these studies be done with a dose low enough to be safe and yet adequate for good diagnosis. In addition, nuclear medicine practitioners are concerned with the public safety and the proper handling of radioactive materials, including the proper disposal of low-level radioactive wastes.

It is our opinion that, rather than consider a lessening of the training and experience criteria, the Nuclear Regulatory Commission seriously consider increasing them.

Specifically, ACNP suggests consideration of the following:

A.	BASIC NUCLEAR MEDICINE SCIENCES	480 hrs.
	1. Nuclear Medicine Physics	80 hrs.
	2. Radiation Biology	40 hrs.
	3. Radiation Safety & Health Physics	40 hrs.
	4. Nuclear Medical Instrumentation	80 hrs.
	5. Radiopharmaceutical Sciences	80 hrs.
	6. Relevant Basic Medical Sciences	80 hrs.
	7. Mathematics, Statistics & Computer Sciences	80 hrs.
	TOTAL	480 hrs.

Note: All of this need not be didactic but could be received in seminars, conferences, and other laboratory experiences.

B. CLINICAL TRAINING

Clinical training should consist of an additional 480 hours, which is <u>not</u> concurrent with the training in basic nuclear medicine sciences (above).

Even though the above suggested criteria are markedly higher that current NRC requirements, it should be specifically noted that these are only criteria for safety and certainly do not ensure

medical competency. Certification by boards, such as the American Board of Nuclear Medicine, indicates far more extensive training and clinical experience and, therefore, medical competency as well as safety.

Concerning the issue of reduction in training and experience criteria limited to cardiovascular nuclear medicine, the College must again urge - no change! At the January meeting of this committee on the same issue, the ACNP stated that there should have been no change in the required number of hours of clinical training. Training and experience criteria should be the same for all physician-users of by-product material. No exceptions should be made!

Cardiovascular nuclear medicine procedures are among the most sophisticated in nuclear medicine practice, in terms of both complexity and instrumentation. The College considers the current NRC training and experience criteria inadequate to guarantee safety; therfore, we can see no valid reason to lessen the criteria for the most critical aspect of nuclear medicine practice.

The ACNP urges that the committee and the NRC review and upgrade all its training and experience criteria for physician-users of radioactive materials.

MR. CUNNINGHAM: The last group that I have on my list is a group of physicians currently completing a training course, and they have asked to be represented by Dr. Phillip Wagner. Dr. Wagner?

DR. WAGNER: I am Dr. Wagner. I am a Diplomate of the Board of Internal Medicine and Cardiovascular Disease, and a Fellow of the American College of Cardiology.

I am in private practice. I represent a group of nine physicians who are at the present time undertaking a training program as proscribed by the NRC.

The recommendations of this group, composed of seven cardiologists, one endocrinologist, and one radiologist, we understand that there is language for requirements to be increased.

We are all in varying degrees of completing our training period. All of us have finished it, and some of us are most of the way through the clinical, some of us are just part of the way through the clinical hours.

We also understand in the past that the NRC has more or less arbitrarily set the dates for changing the requirements. It would appear if this occurs, we will have to revamp our entire training program, if this is done.

Most of the group is in private practice. They have invested heavily in time away from practice and their own time, and very heavily financially, to attain our NRC license.

We hope that a grace period will be granted to the group so that we can finish the training under the present requirements, such as to pose no further hardship upon us.

I would like to go briefly into why I have gone back for training in nuclear medicine. I am a practicing cardiologist in a community hospital which likes to call itself a medical center. The nuclear medicine at this hospital is controlled by Radiology, which is a professional corporation, hired by the hospital.

Most of these people have their nuclear license ~~and~~ on ~~three~~ the three-month program, or less Only two out of three are in the program, and the rest of them have their license on less training.

They do rotate the reading of the imaging and so forth among the group, because different names appear on the reports every month. They do not have a board-certified nuclear medicine individual, and they are not likely to get one in the near future, since they can read x-rays, and indeed they are rotated.

When it became very apparent that nuclear cardiology was a very good diagnostic tool, the cardiologists decided we had better attain it, since we do do 600 open hearts a ~~hear~~ year, and 100 cardiac tests a year.

We met with the radiologist and were promptly informed in the meeting that nuclear cardiology was a cake walk,

and they would be glad to set it up for us. We could come down and monitor the exercise tests. And we said, well, probably this isn't too good in this field.

We were not too sure that their selection of equipment and their diagnostic criteria would be too good. We were promptly informed they had equipment and a license, and could monitor the stress testing part of it. They would like to be present in case an accident occurred.

Fortunately, the equipment belonged to the board of trustees. However, they do have a radioisotope license, and as a group, the cardiologists in this particular institution, all of us are now going back to training to obtain our nuclear license.

We are prepared to meet further stringent requirements, especially as they affect people who are out in the field of private practice. We will perpetuate and protect this type of situation, since it will make it almost impossible to go back for six months' clinical training. Because as far as I know, there is only one such program available at the University of Michigan, and they want $500 a week to do it, plus our time away from our practice and time away from our community.

MR. CUNNINGHAM: Thank you very much, Dr. Wagner.

The point you bring up is extremely important, and we will have to take that into account as we proceed with our deliberations.

Do any members of the committee have questions of Dr. Wagner?

Dr. Holman.

DR. HOLMAN: If the NRC were to change its requirements, what would you consider would be a grace period that would solve your needs?

DR. WAGNER: Most of us are doing this on a part-time basis. Our basic science time was one hour -- I mean one week in a month for four months. We are doing much the same with our clinical experience.

Again, we have to spend time away from our practice, and one of the leaders in this group is the sole cardiologist in the area. It's quite a large area. So when he is away, cardiology shuts down.

I think probably most would like to be given a year if we changed the program.

MR. CUNNINGHAM: Any other questions from members of the committee?

If not, thank you very much, Dr. Wagner. I hope you will be able to stay here for the deliberations.

(The statement follows:)

(5)

1403

RECEIVED

July 10, 1980 [illegible] 59

[illegible]

Director of Nuclear Material
Safety & Safeguards,
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Re: Pending Increase in Training Requirements for Byproduct Material License

Dear Sir:

It has come to our attention that the Nuclear Regulatory Commission ("NRC") proposes to amend its licensing requirements applicable to physicians who read images produced by the use of radioactive materials, or other physicians who practice in the field of nuclear medicine. Specifically, we understand that the present requirement that such a physician have received a minimum of 200 hours of didactic training and instruction is proposed to be increased, with a possible effective date as early as August 18, 1980, to a minimum of 400 hours of such training. It is our further understanding that historically any physician who is unlicensed on the date of enactment of such a change will be subject to the increased instructional requirements.

Nuclear Medicine Associates, Inc., in conjunction with the Picker Corporation of Cleveland, Ohio, has been offering accepted didactic instruction to physicians seeking such licenses from the NRC for the past two years. We are nine physicians enrolled in a course offered for one week per month over a four month period which is due to conclude on August 15, 1980. We will thus fulfill the didactic instruction requirements of the NRC on August 15, 1980 only to be confronted with a doubling of this requirement perhaps as soon as several days later when the proposed licensing requirements may become effective. We believe such a result exceedingly unreasonable and possibly violative of the Administrative Procedures Act and the NRC's own licensing modification procedures.

ATTACHMENT NO. 6

We are a group of physicians engaged in active clinical practice from smaller hospitals and clinics. As such, we have found a course of didactic instruction like that offered by Nuclear Medicine Associates and Picker the most practical means for fulfilling the NRC's requirements. We strongly believe that such a material increase in licensing requirements should (1) be implemented only after affording the public and the medical profession an opportunity to comment upon the proposed change, and (2) at a minimum have a grandfathering provision so that the changes be made applicable only to persons who in good faith have not fulfilled existing didactic instruction requirements by a minimum of 180 days from the effective date of the new requirements. Such consideration is consistent with certifying procedures in medical specialties.

We strongly suspect that the number of physicians affected by the new licensing requirements is substantial. We believe that physicians seeking to practice in the field of nuclear medicine should not be confronted with such a substantial increase in requirements without appropriate opportunity to qualify under existing requirements.

We hereby request that the NRC advise each of us of any response to this letter and of any changes in the proposed instructional requirements and their effective date.

Very truly yours,

Lucy S. Goodenday, M.D.
Associate Professor of
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Toledo, Ohio 43699

John Hess, M.D.
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ATTACHMENT NO. 6

MR. CUNNINGHAM: Dr. Christie of the American College of Radiology would like to make a statement.

DR. CHRISTIE: Thank you very much, Dick.

I am Dr. James Christie, the head of Nuclear Medicine at the University of New Mexico, Professor of Radiology. I am also the Chairman of the Commission on Nuclear Medicine of the American College of Radiology, and responsible for nuclear radiology examinations.

Radiology can accept ~~additional~~ additional training because we feel that our programs are, for the most part, compatible with six months. Since our last meeting, which I believe was in April, we have surveyed the radiologists throughout the country and indeed found that 73 percent of imaging is done by radiologists, and indeed 68.3 percent of radiologists are doing some nuclear imaging, with an average time of approximately 14.4 percent.

I will not accept the argument that the training in the past or the present is woefully inadequate. This I cannot accept.

Likewise, I will not accept that the use of materials [illegible]y is more dangerous than it was years ago. In fact, 10 or 15 years ago, mercury, gold, iodine and other compounds were far more dangerous than anything we are using today.

I don't agree at all with the arguments on waste disposal. I agree with Dr. Webster. In the first place, we

are not even disposing of this any more. We are just allowing all of our materials to decay. So I don't agree with any of this.

However, I do agree that training should be adequate, and this is what we have always argued and will continue to defend.

I should point out that as far as radiology training is concerned, as you all are aware, we have two different programs: one in which we require one year's training, and the other which, for the most part, is three months' clinical training.

The American Board of Radiology will not set a special time for the number of clinical hours. If the NRC requires this in our program, we will just have to coincide with their requirements, or our people will not be able to be licensed in the manner that they are today.

With 63 or 68 percent of radiologists doing nuclear imaging, it is very apparent that a large number of these people out there are not licensed and they are practicing on someone else's license.

There is no problem, as far as we are concerned, if increased training requirements are required. I am sure that the people who want to can obtain this in their practice, as well as working with anyone else.

As far as basic training is concerned, we can live with the present requirements of 200 hours. It has been our

feeling that we are far better off to test for this knowledge, rather than to set a limited number of hours.

But, again, we accept this.

In conclusion, then, radiology can accept this. However I do differ very seriously with the comments that the training today has been inadequate, and that there is something magic that happens with the dimension of nuclear cardiology that makes this a much more difficult field.

If this is true, I am rather disturbed that it takes us about a week or two to teach our technologists to use this equipment.

MR. CUNNINGHAM: Thank you very much, Dr. Christie.

Don't run away yet. I want to find out if somebody has questions for you.

(Laughter.)

Any questions? Any questions by members of the committee?

Dr. Webster?

DR. WEBSTER: I seem to be doing a lot of talking. But it does occur to me that if you go along with six months of total training, which is what radiologists commonly do, it bothers me that that is not consistent with the three-month resident training. You said it was compatible in some way?

DR. CHRISTIE: It is compatible because, as I have told you and told this committee before, our basic science

training is continuous training, beginning the first day of their residency, and continuing on to the last. Our residency programs are now a minimum of three years, and about 50 percent of our residents are taking four-year training programs, with three months clinical nuclear medicine, and this continuing event.

This is at least equivalent to a six-months training period.

DR. WEBSTER: The point is that I think that the people that we heard this morning are not asking for increases on the basic science component. They are asking for increases in the clinical training component, which would mean, it seems to me, a physical presence in nuclear medicine of more than three months, because six months minus 200 hours still leaves a lot of time, like five months, that people would have to be in nuclear medicine.

DR. CHRISTIE: This is not the way I have interpreted the issue.

DR. WEBSTER: I think you may regret the acceptance if you think that the three months --

DR. CHRISTIE: I will accept it on our grounds, not on theirs, then.

MR. CUNNINGHAM: Dr. Holman?

DR. HOLMAN: According to the current regulations for specific licenses, where the requirement is 200 hours of

basic science, 500 hours of isotope handling, and 500 hours of clinical practice, now that adds up to 1200 hours. And the question that I have is, how, if that is looked at in terms of a 50-hour week, that comes out to 30 weeks -- how is it possible to obtain that in less than a six-month period of time, on a basis of current regulations?

DR. WALKER: Can I address that? Just to clarify this, we talk in terms of satisfying this requirement, in part, over some period of time, unspecified. We feel that if it is a part of an integrated program, that the continuous thing can be satisfied with a lesser number of hours, having all the same topics adequately covered in a three-month period.

This is the way it is stated, I believe, in the criteria that we have right now, and this has to be done concurrently.

DR. CHRISTIE: I believe the training is concurrent. It doesn't say that it has to be isolated.

MR. CUNNINGHAM: Any other questions from members of the committee?

Thank you very much, Dr. Christie.

(The statement follows:)

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(6)

July 11, 1980

Mr. Richard E. Cunningham
Director
Division of Fuel Cycle & Material Safety
Office of Nuclear Material Safety & Safeguards
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Dear Mr. Cunningham:

The attached material is sent to you with the compliments of Dr. James Christie. It is the results of a survey conducted by the American College of Radiology on nuclear imaging in May of this year. If you have any questions about this material, please feel free to contact me or Dr. Christie.

Yours sincerely,

Earle V. Hart, Jr.

Earle V. Hart, Jr.
Director, Publishing Services

EVH/lg
Enclosure

ATTACHMENT NO. 5

ACR NUCLEAR RADIOLOGY QUESTIONNAIRE — 3/80

Please complete this questionnaire by placing a check mark in the appropriate box or by filling in the blanks provided for each of the following questions:

1. Are you personally doing any Nuclear Radiology (please check one)?
   ☐ Yes ☐ No

2. Percent time (Example: 10 radiographs to 1 nuclear procedure = 10%)? _____ % (enter number)

3. Board certification (please check appropriate boxes)?
   ☐ (a) ABR ☐ (b) ABR with special competence in NR ☐ (c) ABNM ☐ (d) Other _____ (please specify)

4. Year certified (please enter year in appropriate places)?
   ABR ____ (a) ABR with special competence in NR ____ (b) ABNM ____ (c) Other _____ (d)

5. Extent of formal training in Nuclear Radiology (please check one)?
   ☐ (a) 3 months ☐ (b) 1 year ☐ (c) 2 years ☐ (d) Other _____ (please specify)

6. Is your principal hospital/clinic doing Nuclear Cardiology (please check one)?
   ☐ Yes ☐ No

7. If yes, by whom (please check one)?
   ☐ (a) Radiologist ☐ (b) Cardiologist ☐ (c) Both—cooperative effort

8. If cooperative effort, is arrangement satisfactory (please check one)?
   ☐ Yes ☐ No

   If no, please explain: _____

   _____

9. In your principal hospital/clinic by whom is Nuclear Radiology performed (please check appropriate boxes)?

   In vivo studies (imaging):
   ☐ (a) Radiologist ☐ (b) Pathologist ☐ (c) Nuclear Medicine Physician ☐ (d) Other _____ (please specify)

   In vitro studies (Ria, etc.):
   ☐ (a) Radiologist ☐ (b) Pathologist ☐ (c) Nuclear Medicine Physician ☐ (d) Other _____ (please specify)

10. In your principal hospital/clinic, is Nuclear Imaging within (please check one):
    ☐ (a) Radiology ☐ (b) Pathology ☐ (c) Separate Department ☐ (d) Other _____ (please specify)

    Hospital/Clinic _____

    Address _____

    _____

    _____

REPORT OF THE SURVEY OF ACR MEMBERS CONCERNING NUCLEAR IMAGING

May-June 1980

Early in May 1980, the American College of Radiology's Commission on Nuclear Medicine surveyed the entire physician membership of the ACR as to their activity in nuclear imaging. The results of this survey are herewith presented. Exact totals, and the percentage of physicians who answered the individual question being reported on, are given. In a few instances responses of an impossible nature were received (i.e., one respondent said he received ABR certification in 1980 when indeed at the time of the survey the ABR examination had not yet taken place.) In such instances, even though the impossibility of the response was noted, the result is listed - no attempt at interpretation has been made. Indeed, every attempt has been made to report these data as accurately as possible. The total number of surveys sent out was 10,765.

All of the original source documents from this survey are available in the ACR Washington office should anyone desire to verify the data presented or to garner additional information by combining the results of two or more questions. Inasmuch as there is a degree of confidentiality associated with this material, it is suggested that Dr. James Christie, Chairman of the Commission on Nuclear Medicine be contacted with an explanation of the use to be made of the material desired.

QUESTION 1: Are you personally doing any nuclear radiology?

Of the 4,391 radiologists who responded to this question, 3,001 indicated that they indeed did some nuclear radiology and 1,390 indicated they did none. Thus, 68.34% of the respondents answered in the affirmative.

QUESTION 2: Percent time.

There are several ways to answer this question, and so, a multiple response is herewith presented. Please note that in order to establish the different groups reported on, there has been an association with Question 3, board certification.

Looking at all the 3,001 individuals who claimed to do some nuclear imaging, the average time spent was 14.41%. The range was from less than 1% of an individual's time to 100%.

Concerning the 80 individuals who indicated in Question 3 that they have received a "special competency" designation from the ABR, they spend an average of 25.96% of their time doing nuclear imaging. The range of time spent was from less than 1% to 100%.

ATTACHMENT NO. 5

Concerning the 550 individuals who reported they have passed the ABNM examination (but have not received a "special competency" designation from the ABR), they spend an average of 26.36% of their time doing nuclear imaging. The range of time spent was from 1% to 100%.

Concerning the 71 individuals who indicated they had passed the ABNM examination and had also received the "special competency" designation from the ABR, the average time they spend doing nuclear imaging was 49.18%. The range of time spent was from 5% to 100%.

With regard to all the individuals who said they had received a "special competency" certification from the ABR, or had passed the ABNM examination or both (total 701) the average time spent doing nuclear imaging was 28.63%.

With regard to the remainder of those radiologists (total 2,300) who said they did nuclear imaging (those who have not received the "special competency" certification by the ABR and not passed the ABNM examination) the average time spent doing nuclear imaging was 9.87%. The range of time spent was from 1% to 100%.

Of the individuals who claim that they do no nuclear imaging, 15 claim to have the "special competency" designation from the ABR, 53 claim that they have been certified by the ABNM, and 4 claim both the "special competency" designation of the ABR and certification from the ABNM.

QUESTIONS 3 AND 4: Board certification and year certified.

Not all the respondents to the questionnaire answered these two questions for ABR certification, but it can be assumed that only radiologists responded since the ACR membership list was used exclusively. By the same token, some respondents gave multiple answers to these questions. Therefore, the overall totals will not match the number of questionnaires tallied.

A total of 3,851 respondents indicated they have been certified by the ABR. Years of such certification were from 1936 to 1980.

A total of 170 respondents indicated they have received the ABR "special competency" designation in nuclear radiology in the years between 1974 and 1980.

A total of 878 respondents indicated they have received certification by the ABNM between 1972 and 1980.

QUESTION 5: Extent of formal training in nuclear radiology.

This question was answered by 4,293 respondents. Of this total 2,857 (66.55%) indicated that they had had only 3 months of training in nuclear radiology, 640 (14.91%) had 1 year of training, 114 (2.65%) had two years of training, and 682 (15.89%) had training of some other length of time. The breakdown of the varying lengths of training is a follows:

No training - 78
Seminars only - 8
Residency (unspecified length) - 18
12 hours - 1
1 week - 1
2 weeks - 2
3 weeks - 3
1 month - 20
6 weeks - 4
2 months - 14
500 hours - 1
4 months - 100
5 months - 51
6 months - 286
7 months - 5
8 months - 1
9 months - 26
14 months - 1
15 months - 1
16 months - 1
18 months - 3
20 months - 1
3 years - 16
5 years - 1
6 years - 2

On the job training - 17

2 years - 1
4 years - 1
5 years - 2
7 years - 2
12 years - 3
15 years - 2
17 years - 1
19 years - 1
23 years - 1
24 years - 1
25 years - 1
31 years - 1

Of the 4,293 respondents to this question, 1,065 (24.81%) indicated they had 6 months or more training. Of this total, 880 (82.63%) said they were doing nuclear imaging and 185 (17.37%) said they were not.

QUESTION 6: Is your principal hospital/clinic doing nuclear cardiology?

There were 4,327 responses to this question. Of this total, 2,643 (61.08%) answered in the affirmative and 1,684 (38.92%) in the negative.

QUESTION 7: Who in your principal hospital/clinic is doing nuclear cardiology?

Of the 2,555 individuals who answered this question, 1,480 (57.92%) said nuclear cardiology was being performed by the radiologist, 212 (8.30%) said the cardiologist was performing the nuclear cardiology, and 863 (33.78%) said it was a combined effort.

QUESTION 8: If a combined effort (radiologist and cardiologist) is the arrangement satisfactory?

A total of 113 respondents indicated that they considered the combined effort to be less than satisfactory. Of this total, 43 offered no explanation as to why the arrangement was less than satisfactory. The remainder of the responses are as follows:

- Patients are not referred by cardiology
- Cardiologist does not cooperate in reading of studies
- Cardiologists view nuclear medicine as a threat and thus do not cooperate
- Financial and personality difficulties
- Cardiologist wants to read images
- Desire to do all work in nuclear radiology but need equipment
- No resident radiologist

- Lack of control and delays
- Poor correlation because pathologist does nuclear medicine
- Cardiologists object to double interpretation charge
- Not enough nuclear medicine done
- Too expensive - can be done cheaper by radiology alone
- Significant problems between departments
- Cardiologists stress and inject thalium
- Insufficient support by cardiologists
- Problems of physical location of departments
- Nuclear medicine is under internal medicine
- Cardiologist tries to take over project
- Nuclear imaging performed by pathologist
- Pathologists not trained in nuclear cardiology
- Pathologists do it - and poorly
- Poor expertise in nuclear medicine
- Nuclear medicine not under supervision of radiology
- May become more cooperative as more equipment becomes available
- Administrative problems - only cardiologist can stress
- Scheduling - cardiologist interested in echo and angio
- Problems as to who should do interpretation
- Cardiology and pathology have control
- Internist reluctant to do nuclear imaging and directly compete with their own "basement" stress EKG testing
- Cardiologist shows little interest - perhaps mobile unit would increase utilization
- Cardiology does not send patients
- Little exposure for radiology residents
- Fee splitting - no radiology report submitted

- Political problem
- Access to camera and controls is not limited to qualified personnel
- Cardiologists sending patients to other hospitals where they have greater control
- Each department doing their own studies
- No cooperation
- Cardiologists not referring - doing their own stress
- Scheduling difficulties - not enough history supplied
- Separate facilities
- Cardiologist will not cooperate - does studies himself
- Conflict
- Cardiology trying to take over
- Cardiologist will not review cases - only reads radiologists' reports
- Cardiologist trying to "enter the picture"
- Historic and geographic obstacles
- Nuclear department technically in command of internists
- Time and personnel integration problems
- No fee for services
- No full-time cardiologist and insufficient equipment
- Lack of adequate control
- Would rather see imaging under radiology service
- Cardiologists do most of the interpretation
- Cardiologists want to interpret stress studies but do not have an NRC license
- Cardiologists want to do studies and are discouraging referrals
- Cardiologist not interested
- Done by pathologist
- Technical aspect controlled by radiologist, clinical aspect by cardiologist

- Prime-time coverage only by outside physician
- Political problem - say nuclear cardiology not good enough
- Scheduling problems - minimal reimbursement
- Cooperative protocol being developed with cardiologist and treadmill
- Excluded from this aspect of nuclear medicine
- Cardiologist demands complete control
- No cardiologist in hospital
- Scheduling problems
- Being performed by nuclear medicine physician
- Nuclear medicine under pathology
- Radiologist not required: should be done by cardiologist

QUESTION 9: In your principal hospital/clinic by whom is nuclear radiology performed?

In vivo studies. A total of 4,460 physicians responded to this question - 3,243 (72.71%) said that the radiologist was doing the imaging, 332 (7.45%) said it was done by the pathologist, 811 (18.18%) said it was performed by the nuclear medicine physician, and 74 (1.66%) reported imaging being done by some other medical specialist.

In vitro studies. Fewer responses were received to the second part of this question, a total of 4,161. Of this total 800 (19.23%) said the radiologist was doing this aspect of nuclear medicine, 2,649 (63.66%) said it was the pathologist, 581 (13.96%) said it was the nuclear medicine physician, and 131 (3.15%) indicated that some other medical specialist was doing the in vitro studies.

QUESTION 10: In your principal hospital/clinic, in what department is nuclear imaging within?

A total of 4,145 responses were received to this question: 3,303 (79.69%) said nuclear imaging was within radiology, 219 (5.28%) said it was within pathology, 554 (13.37%) said it was within a separate department, and 69 (1.66%) indicated it was located with some other (unspecified) department.

MR. CUNNINGHAM: I have come now to the end of my list of those that have asked to speak on this topic.

Are there any other members of the audience who want to make some statement at this time?

If not, we will proceed.

I'm sorry. I beg your pardon. Dr. Blahd.

DR. BLAHD: Mr. Chairman, several points have been raised that I would like to comment on, mostly with Dr. Webster.

First of all, the suggestion by all the groups in nuclear medicine that the training be extended to six months implies, I believe, to all of them that this training includes not only the basic science, but the clinical training as well, and encompasses only a six-month period.

I believe what is meant here is not an additional six months, increase the number of months of training.

Secondly, I would submit that as a matter of limited license, with respect to individuals in endocrinology, I would think there are very few people in endocrinology today who are actually doing thyroid uptakes. It is not being done very often.

Those individuals in endocrinology who wish to treat patients' hyperthyroidism, I believe, should be fully and completely trained.

I think it is also true there is no question about that. I think all of you recognize it, that during the last 10 years, there has been an enormous increase in the complexity

and the extent of involvement of physicians with patients and technologists in the field of nuclear medicine, and the regulations we have been living with are about 20 years old. It is time, I think, to upgrade those regulations, and I think it is also fair to say that what we have been saying here this morning has been agreed on by all the people in the field of nuclear medicine who work in this field, they believe that this training should be upgraded, and I think the Commission should consider that.

MR. CUNNINGHAM: Thank you very much, Dr. Blahd.

Before we proceed further with the deliberations, I think we had best, among the committee members, establish the ground rules under which we will consider our present training requirements and any changes to those training requirements.

Basically the Staff has been proceeding with its licensing requirements on the basis that the training requirements for physicians are directed primarily toward radiation safety and reduction of radiation exposure, and this includes radiation safety for the physicians, employees of nuclear medicine laboratories, and the patients themselves.

The reason that we require some clinical training is to assure that the physician is capable of calibrating and administering the correct radiopharmaceutical dose selected for the patients who will benefit from the diagnostic procedure and understanding the limitations of the radioisotope procedures and other similar subjects.

However, our training requirements of the NRC and the basis of these training requirements makes no claim as to clinical expertise of the physician practicing medicine under the license.

Now I would invite the committee members, if they have a different view of the reason for NRC licensing physicians, to state it at this time, because I believe it is very important to have a fundamental understanding of what we are trying to accomplish in the licensing requirement.

So I would ask any members of the committee to comment on this point, so we have a common understanding of what we are trying to accomplish.

Does anybody wish to comment on this?

If not, then I will assume that we all agree that this is the purpose we are trying to accomplish with our training requirements.

With that -- if we are going to take a break, maybe we should do it right now. I would ask that the break be very short, perhaps no more than five minutes. We have a long way to go.

What we will do when we reconvene is review our present training requirements and deliberate on changes that might be indicated from those present training requirements. We do have those summarized.

Excuse me just a moment.

(Discussion off the record.)

DR. WALKER: I just wanted to sort of summarize what I saw in some of the questions and some of the things that have been presented, so the committee could see from the Staff's standpoint what maybe some of our concerns are, and that is first that in the proposal for six months, there was no structure specified, I'm sure that it should be there, that led specifically to the handling of these materials. Expertise related to calibration of the dose, things of this type, the wording of which is currently in our 500-hour requirement, or our three-month requirement, and maybe we can address this later after we come back.

Also we have seen no -- or presented here no justification, really, so far -- there may be, but we haven't had it -- for changes, or to show us that there have been significant differences in the field to warrant these changes that are being suggested. Maybe somebody would like to sort of give us a run-down of why these have changed so drastically in the last couple of years.

We also want to get into something that has bordered on this, and this is the specifying quality versus quantity of training, and I think in the proposals that we have been presented this morning, there has been some, at least, allusion to that, and we are very interested in going very deeply into the limited practices, and we have some additional comments

the Staff would like to make.

But in summary, that is where we stand right now.

MR. CUNNINGHAM: All right. At this time we will take just a few minutes' break, perhaps five minutes. Thank you.

(Recess.)

MR. CUNNINGHAM: Will you take your seats, please.

I believe that we are ready to reconvene the meeting.

We have just completed hearing the oral statements on the first issue, which is general training and experience requirements, and oral statements on the second issue, which is training and experience requirements for limited practice of nuclear medicine.

Just before the break we reviewed the NRC's position on why we have training and experience requirements in our guidelines, and what we are trying to accomplish by those training and experience requirements.

I must say that in listening to the oral presentations, it becomes rather clear that representatives of various professional organizations -- not all of them, but a large part of them -- are in favor of increasing the training and experience requirements.

However, I have not been able to synthesize out of their statements the specific basis for change that we need to establish in order to justify a rule change, and any change would have to be in the context of what we were trying to

accomplish under our regulatory procedure.

At this point I would ask Dr. Walker to review what our present training and experience requirements are, and compare those to the submissions that we have thus far received from various professional organizations, and then followed by deliberation from the committee as to changes that might be appropriate, and the basis for those changes.

Bill?

DR. WALKER: I am going to have to apologize. A couple of people are not going to be able to see this. I hope the committee can see the flip chart.

As I go through, if the various representatives of the organizations that have had input to this either take exception or want to expand on what we see as the position of the various organizations, please let us know. If I talk loud enough, will everybody be able to hear me?

Okay,-I will try this without a mike, since we are having a little trouble.

First of all, we have tried to summarize what our current requirements are for Groups I through III. This is primarily the diagnostic groups. And what the proposals that we have had come out to.

Current NRC criteria for basic radioisotope techniques, the basic training is 200 hours. The experience, the handling experience, hands-on, the types and quantities, 500 hours.

Clinical experience, 500 hours.

We say that with an integrated program, these types of requirements can be met concurrently in the three-month program.

Granted, these don't add up to 1200 hours for three months, but it was considered that these hours might have been collected over a period of up to even a couple of years, in working in various areas to collect this experience and training.

The Federated Council now has proposed, and from their proposal, this is all we really have right now, is that the basic radioisotope techniques still being at 200 hours, but that everything be under a six-month program, which would really exclude picking it up in other than a formal program.

The Board of Nuclear Medicine has broken it down as six months maximum, including the basic handling techniques; 18 months minimum of clinical experience, with a minimum training program of two years.

And, yes, incidentally, this is the same as for certification.

The American Board of Radiology, certification in diagnostic radiology with special competence in nuclear medicine, still talks about a three-year residency, radiology residency program, with one year in nuclear medicine.

Are there any comments from representatives concerning what we have essentially outlined on the chart?

(No response.)

These are essentially what we use right now for licensing. These are the board requirements.

MR. CUNNINGHAM: Bill, does that summarize the basic training requirements?

DR. WALKER: Yes, at this time.

MR. CUNNINGHAM: Okay. Then the issue is should we change those basic training requirements and, if so, how. Does any member of the board wish to comment on that?

DR. WALKER: The question right now, I think the main question is -- and it has been all along -- are these adequate? We have been told by several organizations that have submitted --

MR. CUNNINGHAM: Yes, we have, as I commented just before the break. We have comments from organizations to raise the training requirements, rather nonspecific, and also comments from the same organizations that present training requirements are inadequate.

But, again, rather nonspecific, as to exactly how they are inadequate. So, with that background, I would like comments from this committee.

Again the issue is whether we should change our training requirements and, if so, how and what.

Dr. Workman, I believe, is first.

DR. WORKMAN: I believe the basic training hours or

requirements are adequate, as they now stand.

MR. CUNNINGHAM: Okay.

DR. WALKER: Okay, let's go back to this one.

MR. CUNNINGHAM: When you say that, Dr. Workman, you are talking about basic technology, handling experience, and clinical experience; the whole thing. Is that correct?

DR. WORKMAN: Yes.

MR. CUNNINGHAM: Okay. I was looking in this direction. Dr. Holman next.

DR. HOLMAN: I feel that the basic -- we are talking now only about the basic training requirements?

MR. CUNNINGHAM: Yes. Yes.

DR. HOLMAN: The basic training requirements, I believe, should remain as is, at 200 hours.

MR. CUNNINGHAM: Well, what Dr. Workman was talking about was the whole -- all categories, the basic technology, the handling experience, and clinical experience.

DR. HOLMAN: I believe that the total length of training should be increased to six months. I have several reasons for believing that.

First of all, I think that the current guidelines are inconsistent. If you look at these guidelines, we see that the basic training requirement is currently 200 hours. We see that, in addition, we require experience with the types and quantities of byproduct material in which the application is

made, or its equivalent, another 500 hours.

In addition, we require supervised clinical training in institutional or medical programs, i.e., clinical training requiring an additional 500 hours.

This is a total of 1200 hours of training, and at best in a 50-hour week, it would take approximately six months to acquire this training.

If we look specifically at item 3, we see that there are four categories. One is supervised examination of patients, two, determine suitability for radioisotope diagnosis. Three is follow-up of patients when required, and four is study and discussion with preceptor of case histories.

This is clearly clinical practice, clinical training.

There is a second item here, which is collaboration and calibration of the dose and the actual administration of the dose.

It is my opinion this should be moved to (b) which is experience with handling of the byproduct material. The justification at the present time for a three-month training period is that the training program be integrated. I think this is a semantic error, that certainly the training program should be integrated, but I do not believe it is possible to attain these three disparate training requirements simultaneously. They can be achieved sequentially in the same patient.

Clearly, one needs the basic science, understanding

of the problem, the handling, the dose calibration, the drawing up of the dose, and finally the clinical experience. So it can be done sequentially, but in my opinion, it cannot be done simultaneously.

There is a second reason why I believe the six months training is required, in addition to bringing current regulations into a more consistent pattern, and that is that I believe that the field has become more complex, and the complexity has to do primarily with the tremendous growth of nuclear cardiology, and particularly the development and application of the computer for data acquisition and processing.

And as a result of the complexity of particularly the nuclear medicine procedures and nuclear cardiology procedures, but in addition, other procedures that use the computer, that in fact the complexity of the training for the safe handling of the isotope with particular regard to the data processing and data manipulation has become far more complex than it was in 1976 and 1977, when these rules were first promulgated.

As a consequence, I believe that there is indeed in these particular issues in terms of computer processing and computer handling an increase in the complexity, in the safe handling of the isotope, particularly when we expand it to data acquisition and processing.

Now, as far as the issue of quality is concerned, I would agree that we are right now in a position where we are

dealing with quantity rather than quality. It is getting us in a bit of difficulty, I am afraid.

The problem with attempting to define quantitative measures of competency have to do with certain limitations. I believe the board certification is certainly an index of quality rather than quantity, and if board certification could be the only method of certification, we would find a qualitative measure, but clearly it can't. There has to be a mechanism for individuals who have training equivalency, but are not qualified for a particular board which has certifying capability.

It is for that reason that I believe that the current criteria of 200, 500 and 500 hours be maintained, and the current method of certification by a preceptor also be maintained.

MR. CUNNINGHAM: Thank you very much, Dr. Holman.

I look down at this side. Do any other members of the committee want to make a comment on this?

Dr. Collins?

DR. COLLINS: In the presentation of conflicting interests and opinions, it is quite likely that the agreements can stimulate or state things more strongly than we would in quieter times.

However, it does seem to me that recognizing this point, that we are not going to obtain agreement, we are going to obtain an answer, and it is based largely on the point that has just been raised, or that I raised earlier, that this is a

numbers game, to use a slang phrase. I was listening to the presentation, and it occurred to me that we might be sitting in court, where the comparable use of time is applicable. These are sentences that we are submitting our trainees to, 200 hours of this and 500 hours of that, and 500 hours of this, and as with jail terms, they sometimes may run concurrently.

(Laughter.)

Not to the satisfaction of either the plaintiff's attorney, the defendant's attorney, or almost anybody in court. But we do come up with an answer, and we are willing to settle for that.

To do this, however, it is necessary to borrow another custom of the courts, and this is the adversary system, where opposite sides are presented as strongly as possible.

So if I can be my ordinarily difficult self here, I will try to understand.

MR. CUNNINGHAM: Any other comments, as I look to my right?

DR. GOODRICH: I concur with that.

MR. CUNNINGHAM: Thank you.

Dr. Webster, I think I saw your hand.

DR. WEBSTER: Well, I had the advantage of discussing this with Dr. Holman just about half an hour ago, and I think I have a slightly different view.

I think there is an overlap between these categories

A, B, and C in the present requirements. I think it was intended there should be an overlap, so the simultaneous acquisition of this experience and knowledge could be promoted.

I'd like to hear the official NRC view on that, but as Dr. Holman points out, the supervised clinical training does require as part of it, experience in the calibration of the dose, actual administration of the dose to patients, including calculation of radiation dose.

And that, it seems to me, is also part of the experience in handling radioactivity which is subcategory (b).

It seems to me you can't have it both ways, so to speak. If the same item is included in two categories, then you don't add them arithmetically, you make an allowance for the fact that some of the experience has already been obtained in another category.

Likewise, in the basic isotope handling techniques of 200 hours, it says that included in there would be supervised experience in a nuclear medicine laboratory. That's part of that 200 hours.

Therefore, you don't want to add that particular component into the supervised clinical training and experience of handling the material which are in two other categories.

So it seems to me if you make allowance for that, you don't come up with 1200 hours, you come up with something less than 700 hours, or about 700 hours, which is about four

months, so I could quite readily justify compromise at four months, using your arguments.

(Laughter.)

DR. HOLMAN: It's different mathemathics.

MR. CUNNINGHAM: Thank you very much, Dr. Webster.

Dr. Woodbury, I believe, had his hand up. Dr. Woodbury?

DR. WOODBURY: I'm afraid I have nothing else to offer, except that as I was listening to Dr. Wagner speak, it seemed to me that one of the reasons the dilemma has been created is that in his hospital, as in others, he didn't have a nuclear medicine -- or a person trained well enough in nuclear medicine to consult, advise and handle the nuclear cardiology aspect of their diagnostic procedures.

The same thing can be said in other disciplines, endocrinology and so on. If you are going to have in the hospital or in an institution a nuclear medicine physician who can consult with the cardiologist, who can consult with the urologist, with the endocrinologist, relative to the safe handling of radionuclides used in the diagnostic procedures, I see no way that this type of training can all be circumscribed in a three-month period of time. It just doesn't seem possible to be able to handle, advise and consult with expertise in all the various parameters of nuclear medicine with three months' training. I just don't see it.

MR. CUNNINGHAM: Thank you, Dr. Woodbury.

Any others?

Dr. DeNardo.

DR. DE NARDO: Hopefully not to be repetitious, but I would support the program as outlined by Dr. Holman, which is basically that one outlined and presented by the American Board of Nuclear Medicine and Society of Nuclear Medicine, and I would ask that the NRC consider the fact that basically what you have done in asking the groups involved in nuclear medicine teaching is to get together and come up with this recommendation, is to go to the people who have been involved in the training and say, "In your experience, how long does it take? What does it take?" And from testing people for what they know after so much training, that has to be a mean, because obviously there are people who fall on both sides of that mean, low and high.

What is a reasonable amount of training to make people adequately safe in the use of radioactive material for diagnosis and therapy? But particularly for diagnosis and internal use.

You have asked people who have taught this for years, who have examined for years, and they have come back with a recommendation, and now you say why are more than three months necessary? And I agree with you, having been in the curriculum for about three years, that it is hard to correlate quantity and quality, and it is hard to measure quality.

In fact, it is difficult for even people doing certification boards to give a written examination, and know that the person who has answered those questions correctly, can indeed safely use the material on a patient. Writing down a black-and-white answer is quite different from actually using it.

Not to be long-winded, but I would like to say that people after three months of training in the programs that we have seen, come back with all sorts of problems to the institution where they are trained. We get phone calls all the time asking what to do and how to go about it.

Three months has not proven adequate, and the people who have been sitting in institutions answering questions can tell you the students they have had for three months as a mean -- not the exceptional individuals -- cannot do an adequate job of safely using these materials on a patient.

On the other hand, there are individuals who, after two years, cannot, either, but they are the exception, and there are rare individuals who, one might at least raise the question, might be minimally adequate after three months. They are indeed rare.

So I speak very strongly to support the proposal as a minimum requirement for the six months.

MR. CUNNINGHAM: Thank you very much, Dr. DeNardo.

Any other comments? Dr. Griem.

DR. GRIEM: I think the Commission and this Advisory

Committee are responsible for safety of the body public, and ultimately the efficacy with which these tests are used.

Now if you consider that from one vantage point the radiologists have had extensive training in image quality, image analysis, and so forth, and on the other side, the cardiologist has had extensive training in his needs, I think that each of them present certain requirements, and that as you try to integrate this all, the Federated Council has come together and suggested six months, and that seems to be a very logical answer in this very rapidly developing field, where equipment and sophistication have moved ahead very rapidly in the last two or three years.

MR. CUNNINGHAM: Thank you, Dr. Griem.

Bill?

DR. WALKER: May I make one comment? I would appreciate it if the members, when they make their proposals, make their statements, clarify this for the Staff. There are two issues that are fairly basic to this, and that is the hours as such can be picked up by someone over a period of time in other than a formal course.

The other one that we have been talking about, three months versus six months, is generally considered to be a formalized training program, one such as might be approved by the Liaison Committee on Graduate Education. This is a basic issue we need to know, whether or not you are saying to drop the

informal portion of this and have a requirement that all of this be under a formal program, or whether you are considering maintaining both of these routes towards NRC approval.

MR. CUNNINGHAM: I think I will try to get to that in my summary.

Dr. DeLand?

DR. DE LAND: I would like to make one comment on your point. From experience, certainly it is quite feasible to get the basic training as an intermittent thing, preferably related to some type of formalized course situation. You know, two or three times a week, or whatever it might be.

But once the clinical aspect is entered into -- now I'm talking about the handling of patients, the relation and so forth -- I have found it extremely unsatisfactory to do this on anything but a full-time basis.

I do not approve of persons coming in once or twice a week trying to get experience. It's a fractionation that I think detracts from the training, and at my institution I won't accept it.

MR. CUNNINGHAM: Thank you, Dr. DeLand.

Any other comments from committee members on this subject?

Dr. Webster?

DR. WEBSTER: It's nice to be the last man.

MR. CUNNINGHAM: I'm not sure that you are.

(Laughter.)

DR. WEBSTER: As I see it, the issue really is the one of clinical experience, which the Commission should require. There is no argument about the basic technology issue of 200 hours.

Now, that 200 hours is about five weeks, if you did it on a full-time basis. At the present time, then, in addition to that, the Commission requires eight weeks to establish that the individual exhibits a consciousness of radiation safety in the administration and care of patients.

I emphasize radiation safety because we are not talking about clinical competence. If we are talking about clinical competence, we might like to push for the whole two years, which the American Board of Nuclear Medicine is demanding.

So, obviously we have to settle for something less than that. So we now have a five-week basic training period, an eight-week clinical period.

What is being suggested to us is that the eight weeks be expanded to 21 weeks, in the clinical area. That is five weeks basic again, plus 21 more extra weeks to get up to six months total. That is a factor of almost three expansion of the clinical component, and I seriously question whether such a large increase, particularly since the purpose of the Commission is not to establish clinical competency per se, but only safety, is really justified.

MR. CUNNINGHAM: Does anybody wish to comment on Dr. Webster's point? Is it on this point, Dr. Woodbury?

DR. WOODBURY: I think that it is just on this point, where the nuclear physician is supposed to have some element of expertise in many areas of diagnostic nuclear medicine, handling, safety, dosimetry and so on, in all fields of medicine.

As I mentioned before, to consult with cardiologists, urologists, endocrinologists.

My suggestion is that in order to gain the experience and the expertise, in order to do what he holds himself or herself out to do, it takes more time, it takes more time than three months, all-inclusive, that we now have.

It would seem to me that in order to protect the patient's safety in terms of the administration of radio-isotope in all the spheres of medicine that nuclear medicine impinges upon, it takes more than just the required period of time now.

MR. CUNNINGHAM: Thank you, Dr. Woodbury.

I believe Dr. DeNardo was going to say something.

DR. DE NARDO: I was just going to add the answer to the question was raised, does it indeed require this much increase? Yes, sir, it does.

MR. CUNNINGHAM: Capt. Briner?

CAPT. BRINER: I would like to remind the committee that one of the presentations this morning, there was quite a

drastic increase in the so-called basic science component of the training requirements from the ACNP which increased that basic component from 200 to 480 hours. I think that needs to be recognized, at least that that suggestion was made.

MR. CUNNINGHAM: Any other comments by members of the committee?

Dr. Collins.

DR. COLLINS: I hope this isn't too facetious, but it does appear to me, as I listen to this, and as I stated in my previous comment on sentencing, whether the sentence is for educational purposes or deterrent purposes.

(Laughter.)

MR. CUNNINGHAM: I think we have to bear that in mind as we go along.

(Laughter.)

DR. COLLINS: I want the punishment to fit the crime.

MR. CUNNINGHAM: Any other comments?

Let me try. I think we have pretty well explored the subject. Let me try to summarize where I think we are coming out on this. Based on what I have heard here in our deliberations, although we don't have unanimity among the committee members, I would say that some consensus appears to be emerging, and that is that the basic training requirements of 200 hours, the handling experience at 500 hours, and the clinical experience of 500 hours, in themselves are probably

appropriate.

The aggregate, how these are aggregated, though, comes into question, and the issue is whether that should be three months or six months of a formal training course which would be a full-time course, or the equivalent of a part-time course.

As I said, the committee believes, or there seems to be some consensus that the aggregate training should be somewhere around the six months, maybe four months, as Dr. Webster suggested, or maybe somewhat higher than six months, as some others have suggested. But it seems to center around the six months training course.

But the basic hours essentially as they are, but aggregated in a somewhat different way.

Does that seem like a fair summary of what has been said?

All right. The next question on this that Dr. Walker raised, and Dr. DeLand addressed, was whether or not this should be a full-time course, or whether it should be permitted to be broken up into part time or some other way, how this aggregated six-month training is developed.

I would suggest that at this time we allow some flexibility for the specific training institutions to do this as they see best fit, and not get into that.

Do I have some consensus from the committee on that?

If there are no comments on that, we will proceed

on the basis that that should be a decision of the individual training institutions.

Do you want to make any comment on that?

DR. WALKER: No.

MR. CUNNINGHAM: All right. Well, if that is the case, the Staff will proceed along the advice given by this committee on what seems to be something of a consensus, and proceed along that basis.

I will make the statement that based on this advice, and any training requirements that change following this, we will do two things:

First, we will give some long-range notice, so that people have ample opportunity to change their curriculum and training course.

And, secondly, for those who are in training or who have already completed their training, but have not yet been put on a license, we will take into account the change, and we will consider some sort of grandfathering way.

Do the committee members wish to comment on this subject? Dr. Holman?

DR. HOLMAN. I just think that it is very important that some grandfathering, some period before these regulations go into effect, so the individuals who are currently in the programs are protected.

MR. CUNNINGHAM: Yes, I think Dr. Wagner, in giving

testimony here, brought up a very important point for us to take into consideration.

So any proposal we put out based on this meeting to change the requirements will have a lead time for the training institutions to change their curriculum, to not interfere with classes that are already scheduled and maybe in progress, and also some grandfathering statement.

If that is all on this subject, I think we can move on to the next subject, which has been discussed in part, and that is the training and experience requirements for limited practice of nuclear medicine, such as may be the case for cardiologists, endocrinologists, and so forth.

Bill, do you want to proceed with this?

DR. WALKER: Yes. I think probably it would be best to discuss these in two separate parts, the cardiology first and then go to the other limited procedures such as endocrinology, and opthalmology, I think is an important one, too, here.

Currently as a result of the last ACMUI meeting, we established that for physicians limiting their practice to nuclear cardiology, the requirements would be essentially the same as those for Groups I through III.

However, since the number of procedures was much more limited, that we would make some adjustment in the number of hours of clinical experience, and this was actually cut in half.

This particular set of criteria was published and received an awful lot of comment.

(Laughter.)

But this is our current criteria. So I think some of the things we want to talk about, is there really justification to say that nuclear cardiology is that different from the rest of the practice of nuclear medicine, such that the experience should be lowered, and are our current criteria the minimum necessary to ensure that physicians are adequately trained to handle byproduct materials safely? And if they are not, how and why should they be changed? That is what we need right now.

MR. CUNNINGHAM: All right. Does any member of the committee wish to comment on this?

DR. WALKER: I might say that the Federated Council's proposal for nuclear cardiology was that they satisfy the same requirements they were recommending for Groups I through III, which was a six-month program to incorporate at least 200 hours of basic radioisotope handling techniques.

MR. CUNNINGHAM: I believe that was supported by the American College of Cardiology this morning, was it not?

DR. WALKER: Yes, it was.

MR. CUNNINGHAM: All right. So what we have heard from the Federated Council and the cardiology folk would be to endorse the same training requirements, the same length of

training as is the case for physicians who want to practice a broader spectrum of diagnostic procedures. Our present training requirements are less than that.

Do any members of the committee wish to comment on this? I do need some assistance from one position or the other position. If anybody wants to comment.

If not, I will call upon each of you to take some position. Dr. Holman?

DR. HOLMAN: Well, I have a problem taking a position. Let me explain the problem. I see what has arisen, primarily, in my mind, at least, as a semantic issue on this point with concurrence of the American College of Cardiology, and basically the same training requirements as that of the Federated Council and Society of Nuclear Medicine.

The issue I see is the primary one, in my mind, is that a physician who has limited his training to a particular area -- in this case, for example, it would be the applications of radio tracers in the heart -- having fulfilled the requirement suggested by the American College of Cardiology and other organizations, should be able to attain an isotope license, a specific license, based on his limited exposure to the spectrum of radiopharmaceuticals and procedures, and should have his license in some way restricted by the NRC to perform those procedures for which he has experience.

As long as that can be accomplished under current

or planned procedures, then I think the concept of a limited license in cardiology becomes a semantic one, as long as the individual is able to obtain a license and have it restricted in its use to those procedures and those radiopharmaceuticals for which the individual was trained.

MR. CUNNINGHAM: Well, then, are you suggesting that we should keep our present training requirements and not change them?

DR. HOLMAN: I'm saying this is based on the assumption that one would change the requirements to what I previously recommended, six months.

MR. CUNNINGHAM: To six months.

DR. HOLMAN: Exactly.

MR. CUNNINGHAM: So that you're suggesting that the total training period cover for a full-time course would be six months, with a breakdown of distribution of the training along the same lines. All right.

Does anybody else wish to comment? Dr. Goodrich?

DR. GOODRICH: As it was just explained to us during the break, the present procedure, I believe, that's being practiced by the Staff is to indicate the licensee has permission to practice within the limits of Groups I through III. That's on one line.

But then under "comments," it is implicit, I believe, or some other place in the license, it is implicit that his

practice and his activities be limited to those that pertain to the specific radionuclides and the clinical applications of those nuclides.

I gather that that has some muscle beyond the level of Groups I through III, which are far more inclusive. But I also am a little bit concerned that that may not be as clear in the public view -- it is obviously not quite as clear among these committee members. And if it is not clear with us, then how clear is it with the people who -- pardon me -- the enforcers who go and inspect, and just how well is this going to be managed and implemented beyond the level of the individual physician and his practice?

DR. WALKER: If I may interject, the license itself is very explicit. It says what materials you may use and in what quantities you may use them, and for what purposes you may use them. These are very specific items on every license.

It also names the individuals. As far as the information is readily available to anyone who has this license. And this is the point we try to make, is that license should be read when it comes in. If they don't read it, they don't know what they're authorized to do.

Now as far as an individual, Dr. Holman referring to an individual being limited, each individual's training and experience, when it comes in, is thoroughly evaluated to see exactly what materials, what procedures he has the experience in,

and what he is authorized to do. So that is covered.

MR. CUNNINGHAM: Dr. Webster?

DR. WEBSTER: I'm probably going to be speaking for the minority again, but that's fine. Right now on Appendix A we have a Section 2 which says training requirements for specific diagnostic procedures -- it's quite short, and I would like to read it to you.

> "A physician who wishes to be authorized for only one or two specific diagnostic procedures should have training in basic radioisotope handling techniques and clinical procedures commensurate with the procedures and quantities of byproduct material being requested. Such requests will be examined on a case-by-case basis by the Commission with the assistance of the Advisory Committee on the Medical Uses of Isotopes."

I submit that applies quite strongly to the people who want to do a limited amount of endocrine work. For example, they want to do thyroid scanning. And I would think it would be very onerous to insist that those people should have six months of overall training, which seems to be the drift of this particular meeting.

I would feel strongly that the special consideration of people who don't want to do the whole gamut of nuclear

medicine should continue. I think it is only fair to those physicians.

MR. CUNNINGHAM: Dr. DeNardo?

DR. DE NARDO: I'd like to start with your specific example, in that perhaps one of the best examples to the contrary for my reason for not agreeing with the entire concept is the section that you have just read. It is exemplified by the thyroid scans that we see by people only doing thyroid scanning. You frequently cannot read them. They are technically usually not -- the ones we see brought in or sent for technically are done in such a manner that they were a disservice to the patient.

I have seen many examples of that, and I think my colleagues and other colleagues in this room can recite those examples, too.

What we are talking about is that except for a few procedures which I think can be picked up and perhaps may or may not justify major exemptions, usually for the patient's usage, diagnostic procedures of radioiosotopes, the basic radioisotope, physics and chemistry and radiopharmaceutical and dose calculation and instrument calibration, and the ability to put this into patient care, those multiple hours of training we were just discussing in terms of the general uses, are all necessary in order to do a safe job and an adequate job of applying radionuclides to the diagnostic practice of medicine.

And so I don't think it is different if you are just

doing thyroid scans. You can do a disservice in thyroid scanning if you don't have the other background, and I think that this has been borne through in many, many clinical practices.

MR. CUNNINGHAM: Dr. Webster, do you want to rebut?

DR. WEBSTER: It's obviously a very small subset of the total picture. One must bear in mind that the performance of a thyroid uptake test is now permitted under a general license to physicians and requires no basic science training at all. However, many thyroid specialists who practice therapy with I-131 can already meet the required 80 hours of basic science training which includes instrumentation.

DR. WALKER: If I may, can we still separate this out, the cardiology from the rest a little bit? We sort of moved into the next subject.

Was it the consensus of the committee that cardiology would be essentially the same, recommended that it would be essentially the same as Groups I through III, with limiting the individual to those procedures for which he has experience?

MR. CUNNINGHAM: Well, let me try to summarize now.

First, we have had reports by the Federated Council as well as the American College of Cardiology, supporting the six months of training program, equivalent of training for Groups I through III, although the emphasis may be somewhat different.

I gather that most members of the committee support

this. For that reason, I believe that the Staff will take under consideration a proposal to require six months' training, with appropriate breakdown of training for cardiology.

Is that generally agreed? I take it that is general agreement.

The question of training requirements for other specialty groups, particularly the endocrinologists, for diagnostic -- and we're not into the therapy yet -- but for other diagnostic procedures, I think requires a lot more study and consideration than it has been presently given.

As response to one of Dr. Webster's questions, at the outset of this, was whether the Federated Council had representation by other specialty groups in coming up with a six-month training requirement, and I gathered the answer to that was no, with the exception of the cardiologists. I believe that until we get a better feel for the range of diagnostic procedures we are talking about, that we had better handle these on a case-by-case basis.

I believe that should be a subject for further consideration at another meeting. However, I would like in the interim to get some commitment from the Federated Council and various professional groups, if they will get together on this point and try to achieve some consensus as they did for cardiology.

So with respect to cardiology, I believe we should

proceed on the basis of six months, and with respect to some of these other subspecialties, I believe this requires further consideration of the Staff.

Dr. Woodbury?

T.4 DR. WOODBURY: I'm just going to express an unpopular position. It really distresses me to see, after all the years of work and endeavor that has gone to establishing the discipline of nuclear medicine and the boards of nuclear medicine and criteria for training and experience in nuclear medicine, that we would now begin to fragment. Because if we now fragment out the cardiologists, then why can't we then fragment out the endocrinologists and the urologists and the chest people and so on?

It seems to me that if we are going to develop the criteria for a discipline that can impact and impinge on all the diagnostic analyses of nuclear medicine, that we are ill advised to continue down the trail of fragmentation.

I realize the difficulties that this employs, and so on, but certainly for the short haul for the next few months, it is perhaps prudent to fragment. But for the long haul, it seems to be an ill advised route to take.

It seems to me that all the work that has gone into establishing the boards of nuclear medicine and the criteria for training, so on and so on, that, too, at this point in our development now begin to fragment off groups that cannot look at or cannot deal with or cannot utilize the whole area of nuclear

medicine seems to me to be ill advised.

MR. CUNNINGHAM: Thank you, Dr. Woodbury. I can appreciate your concern. However, I question whether it is the role of a federal agency to address that concern. I think this is more a role that should be addressed by the profession itself, rather than a government agency, as it does in other fields of medicine.

Basically if we go back to our initial premise, our principal concern for federal regulation in this field is to ensure some degree of safety in the use of these materials without addressing the question of the quality of the practice of medicine.

I believe that the basis for restricting some fragmented groups or specialty groups, if you will -- I really think this is a question that has to be resolved within the profession itself through the various boards, and not through a governmental agency.

I see an arm, but I can't quite see who it's attached to. Dr. Workman.

DR. WORKMAN: I would like to ask a question. How big a problem is this, really, in numbers? Are there a lot of people who are interested in just doing thyroid scans?

DR. WALKER: There are a fair number of applications for this type of thing.

DR. WORKMAN: Specialty things only?

DR. WALKER: I don't have specific numbers on it, but we do receive these requests on a regular basis.

MR. CUNNINGHAM: Dr. Webster?

DR. WEBSTER: Just to comment on Dr. Woodbury's attitude, and that is what he is suggesting is that if we were to apply his opinion to x-ray diagnosis, that cardiologists and orthopedic surgeons should not operate x-ray machines. I think that is far beyond the competence of a group like this to determine, and I think the parallel is very apt.

MR. CUNNINGHAM: Dr. Goodrich?

DR. GOODRICH: I would make the observation, based on what Mr. Cunningham stated, that it may be inappropriate at this point for NRC to hear and to act favorably on the consensus of the Advisory Committee with respect to cardiovascular and nuclear medicine, and at the same time establish a different caste system for applicants from other subspecialty areas, which could be perceived as an implication that those other areas of medical practice lack the complexity or perhaps have greater complexity and greater potential impact on the medical community.

So I believe it would be my recommendation that the six-month training period be looked favorably upon, and applied to all applicants for, quote, the limited license, or what-have-you.

MR. CUNNINGHAM: Well, I believe my position may

have been a little bit misunderstood, Dr. Goodrich. I first said that we were not going to come to a consensus of opinion, except with the cardiology and subspecialties.

I did not say that we were going to apply different criteria to the other specialty groups at this time. What I said was that we will consider these on a case-by-case basis, but not come to a specific understanding which would serve as the basis for advising as guides.

I am concerned that groups like endocrinologists apparently have not been consulted on these things. I don't know if it makes any difference, but nevertheless I think it is premature to lock in on this, if we haven't given them an opportunity to explore this.

We will be consulting with members of the committee as specific cases come up, and then we will try to write a conclusion on a case-by-case basis on these other groups.

Dr. Collins?

DR. COLLINS: I think if I understand correctly, Mr. Cunningham, what you have said is that again we must have an answer, this is a day in court, this is open to review and consideration.

For instance, I don't think we have enough information really to pass on this. No one here today has mentioned what these tests are that endocrinologists would like to do. There has been nobody to speak for or against them.

The two major ones are the scanning and the blood pool detector or appraisal, and there are cardiologists who don't think that either one of these are very important. And we might well be making a mountain out of a very small molehill here.

So we need more information to really appraise this.

MR. CUNNINGHAM: Does somebody wish to comment on Dr. Collins' observation?

Dr. Holman.

DR. HOLMAN: We have representation from the American College of Cardiology. Perhaps could we ask them to address that point?

MR. CUNNINGHAM: Yes. Let me get out my list. I'm sorry. Will you step up and perhaps address Dr. Collins' points?

DR. BORER: I am Jeffrey Borer.

If I understand correctly, Dr. Collins, you are asking what procedures the cardiologists are requesting certification for.

DR. COLLINS: Some cardiologists are requesting and some may not be.

DR. BORER: Yes. Some cardiologists are requesting certification for the use of isotopes. Basically there are three clinically-applied techniques in nuclear cardiology today.

One, as mentioned, is myocardial perfusion scintigraphy, which in the clinical field today involves the

use of the isotope Thallium-201.

The second would be radionuclide angiography or blood pool scanning, using Technetium 99^{m}, and that procedure might be considered as involving the use of Technetium labeled ~~for~~ human serum albumin, and also the use of Technetium labeled to red blood cells by one technique or another.

And the third would be Technetium pyrophosphate scanning for myocardial infarction. That is myocardial infarction detection with infarct-avid agents. These would be the clinically applied tests today.

There are, of course, several other techniques which are in the experimental phase right now that might be found to be clinically valuable later, but these are the techniques we are talking about today.

MR. CUNNINGHAM: Thank you very much.

It is my impression that the cardiology procedures have been pretty well explored by this committee and by groups we have asked to look into this, the Federated Council with various professional representatives, professional group societies, groups and boards represented in the Federated Council.

I don't think that is the case for other specialty groups. So I would, with what I believe is the consensus from the board, proceed on the basis that we have enough information about cardiology to agree to what has been outlined thus far,

but we should hold off on the others and seek further consultation on that.

Any further comments?

If not, I think it is getting late. We should move on.

Bill, what is the next subset?

MR. WALKER: The next subset is the therapy in Groups IV and V -- and there are two questions here. The first one is again the limited license, and what we currently do in the second one would be -- I think we'll probably wait on that -- for the American Board of Nuclear Medicine, and whether or not to accept certification by that board for groups IV and V. But I think we ought to cover that later.

Essentially we have been in the past for any of the procedures under Groups IV and V requiring 80 hours of basic radioisotopes handling techniques and preceptor-specific experience, a certain number of cases depending on a procedure being authorized.

Under the Federated Council's proposal, they would eliminate this limited authorization and require anyone getting an authorization for these therapeutic groups to again get the six months' integrated program, incorporated the 200 hours of basic radioisotopes handling techniques.

And the question is now, as it has been, are our current requirements sufficient in these cases to ensure the

safe ~~the~~ use of these materials? If they are not, how should they be changed?

MR. CUNNINGHAM: Dr. Griem?

DR. GRIEM: In radiation oncology, it appears that some of the liquid isotopes are becoming popular, particularly phosphorus for ascitic ~~cancerous~~ tumors and so forth.

Now if one considers that in treatment of cancer of the ovary Stage III, for instance, this is really an integrated, combined treatment consisting of some medical oncologies, nitrogen mustard, and a half dozen other alkylating agents, and ~~antimetabolites~~ anti-metabolites combined possibly with radiation therapy, which requires a third degree of dosimetry and sophistication, put together with radioactive P-32, then I wonder if the proposal there really covers that correctly.

I would guess not, when you start working on the questions of strip radiation therapy, dosimetry, and start considering aspects of the medical oncology involved, and I wondered if the Federated Commission would like to talk a little bit further about that.

MR. CUNNINGHAM: Is anybody present representing the Federated Council? I don't believe there is anybody that can speak for the council itself, which is rather unfortunate.

Do any other members of the committee want to comment on this point at this time?

Dr. Workman.

DR. WORKMAN: I think that the 200 hours, as proposed, would be adequate for basic techniques, but I do think that there should be a specific number of cases where procedures should be added to that. I think this came up back in January when we talked about it before, where there were people who might not have had really specific case experience, and it can be very important, rather than just the general feeling of the whole group.

MR. CUNNINGHAM: Thank you, Dr. Workman.

Dr. Webster.

DR. WEBSTER: I am concerned about the -- strangely enough, about the clinical requirements for Group V.

(Laughter.)

It seems to me that there is a dichotomy here. In Group IV where we were talking about iodine-131 for treatment of hyperthyroidism, where we require active participation in the treatment of 10 patients. When it comes to cancer therapy, you only have to have active participation in the treatment of three patients. And I would think it might go the other way, and at least I think there should be some equality there.

So I would support some increase in the clinical requirements for cancer treatment by iodine-131 of less than the minimum.

With regard to the basic radioisotope handling techniques, I think one must also look at what is required for

Group VI, which is the basic radioisotope handling techniques for sealed sources. For sealed sources, 200 hours is being required, and I am wondering if indeed these are less hazardous -- or, excuse me, more hazardous than the unsealed sources. I would have guessed it was the other way around, that unsealed sources present more problems than sealed sources.

And so I would think that there might well be some increase in the basic radioisotope handling technique component for Groups IV and V. I'm not sure I'd go all the way to 200 hours, though.

DR. WALKER: While we're talking about the number of cases, the way it is written is a little misleading. However, for the Group V, the cancer therapy, that is the three treatments plus the 10 that they had to have in the treatment of hyperthyroidism. So the three cases would be in addition to those. So it is a larger --

DR. WEBSTER: Well, suppose somebody comes in for Group V only, which is cancer treatment with iodine-131.

DR. WALKER: We require that they work with hyperthyroidism as well.

DR. WEBSTER: That's not at all clear the way it is written.

DR. WALKER: I know it. We have a new revised guide coming out very shortly that makes that much clearer.

DR. ALMOND: I just wanted to support Ted on the

Insert - Page 93a

HARVARD MEDICAL SCHOOL ◆ MASSACHUSETTS GENERAL HOSPITAL

DEPARTMENT OF RADIOLOGY--
Division of Radiological Sciences and Technology

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Boston, Massachusetts 02114
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August 19, 1980

Mr. Richard E. Cunningham
Director
Division of Fuel Cycle and
Material Safety
Office of Nuclear Material
Safety and Safeguards
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

RE: Changes to ACMUI regarding August 18, 1980.

Dear Mr. Cunningham,

Since the ACMUI Meeting yesterday, I have had time to reflect further on some of the opinions I voiced, particularly with regard to the present licensing requirements for Groups IV and V. Actually I did not realize that the adequacy of the requirements for these particular (therapeutic) uses would be raised during the meeting since the agenda item appeared to be related only to whether diplomates of the ABNM should be automatically approved for such therapy. My comments were therefore made on the spur of the moment without the more reflective consideration which I would have preferred. Therefore I wish to modify my remarks regarding groups IV and V.

1. Please therefore add the following comments with regard to the clinical component of Group V training with regard to thyroid cancer treatment. These remarks should follow my response to Dr. Walker in which I said that the interpretation of the 3 required cancer cases as being in addition to the 10 hyperthyroid cases (Group IV) was not clear in Appendix A.

"I suggest that the explicit inclusion of say 5 hyperthyroid cases together with the current 3 required cancer cases would be adequate. I recognize that even in a large general hospital, relatively few thyroid cancer cases are treated per year (at the Massachusetts General Hospital approximately 10) and therefore personal participation in the treatment of more than 3 or 4 such cases would be difficult during the course of a training period of the order 6 months. The management of hyperthyroid cases has some similarities from a radiation safety point of view to that of cancer cases and therefore their inclusion explicitly would increase the relevant experience of these trainees."

(End of first insert)

Mr. Richard E. Cunningham
August 19, 1980

Insert-Page 93b

With regard to the 80 contact hours for basic science and handling techniques I have had more important second thoughts. I noted in my comments that the 80 hours seemed inadequate compared to the 200 hours required for sealed source licensure in Group VI, on the basis of protection problems. At the end of those comments I noted "I'm not sure I would go as far as 200 hours." I would like now to modify and expand those comments and be more specific.

2. Please delete from the record that last sentence ending "200 hours" and add the following material:

"However, on more detailed consideration I believe 90 hours or at most 100 hours are adequate for Groups IV and V. There are of course obvious differences between the use of several different isotopes in sealed sources for brachytherapy and the use of only one isotope, namely I-131, in unsealed form for thyroid treatment. The dosimetry and treatment planning for the variety of sealed sources used in brachytherapy is far more complex than that for I-131 use in therapy; the latter is selected on a more empirical basis. The instruction, particularly regarding in vivo measurements in patients and treatment planning techniques is also considerably more advanced. While there are increased protection problems arising from contamination with I-131, these are counterbalanced by the greater exposure rates encountered near brachytherapy patients, the need for leak testing of sources, and source storage and shielding problems arising from longer half lives and greater penetration of the radiations used. The range of mathematics needed for I-131 therapy is less than that needed for brachytherapy, while the radiobiological training is also more limited because of the unique use of I-131 with one temporal pattern of delivery in thyroid therapy."

"In addition, one must bear in mind that brachytherapy is usually administered by radiotherapists who receive in-depth radiation physics and radiobiology training in connection with teletherapy practice which justifies the acquisition of 200 hours overall contact hours in these basic sciences, usually during a 3-year radiotherapy residency program: whereas treatment of hyperthyroidism and thyroid cancer is frequently practiced by thyroid specialists who are not involved with any other kind of radiotherapy. For all these reasons, therefore, in my considered judgement I believe that the 80 hour requirement for basic science and handling techniques under Groups IV and V is reasonably adequate. If others believe that some increase beyond 80 hours is needed, I could not support an increase beyond 100 hours."

(End of second insert)

Yours sincerely,

E. W. Webster

E. W. Webster, Ph.D.
Prof. of Radiology (Physics)
Member, A.C.M.U.I.

cc: W. J. Walker, Ph.D., NRC
Mrs. P. C. Vacca, NRC
M. Griem, M.D.
V. Collins, M.D.
P. Almond, Ph.D.

EWW:mcr

increase in the 80 hours there. I have never understood why that particular group had less than half of all the other Groups that we have had, especially when they are handling higher activities, radioactivity, and the inherent danger in that is much more than in the diagnostic use, and in the sealed sources. And I would think there should be a uniformity in the basic area for all the categories.

MR. CUNNINGHAM: It seems to me you're going to have to go to almost 200 hours to be able to interpret the administration rules on it.

(Laughter.)

I gather from what people are saying that we have 200 hours and six months for the other Groups. This is substantially less, as it currently stands. I think there is little rationale for being less, particularly in light of some of the new procedures that may be coming on, as Dr. Griem describes.

I gather that the consensus of the committee is to make them more or less equivalent to the other Group training requirements; is that where we come out on the committee? I see heads nodding yes.

So that is the basis upon which the Staff will proceed.

Okay, Bill, what is the next subject?

DR. WALKER: The next subject has to do with improved documentation of training and experience. I believe all the

committee members received a revised Supplement A and B. We have for some time had some problems with this.

I think now since I am finished with the flip chart for a while, I will go back and sit down.

(Pause.)

Very briefly, what we have are Supplement A, which refers to documentation for the basic training described as 200 hours under our current requirements. It is somewhat confusing as it is written now. It is an abbreviated form with a very wide range of documentation from a very nonspecific notation that some time in the last 10 years, they took a course somewhere, to transcripts and everything else. This one should make it a much more clear requirement.

It requires in addition to that certain things:

One, a statement by the program director or some representative of the program director, stating that the individual has successfully completed the program.

At least one example from one program where an individual had completed his 200 hours, we found that that individual had been absent a number of times from the course. He had gotten a grade of 30, where the course director had normally considered 70 as passing, but he had a certificate of completion from that course, and used it to satisfy the requirement.

We can hardly consider that individual qualified to safely handle these materials. Yet, using the previous form,

this was acceptable.

So it is revised in those aspects.

It is further revised in that it makes it known that this is an official form, something that was inadvertently left off of the current ones. So that the individual is at least legally responsible for anything he puts down on this form.

There is a little bit more specific information asked for, especially where it comes to the types and qualities of isotope that have been worked with.

DR. WOODBURY: Under 5(a), we have experience with radiation, and you only have room for one isotope, or maybe two at best. But there are a list of isotopes for which you might need the same information.

MR. CUNNINGHAM: I think the answer to that probably is it was just to conserve space. But you can make an attachment, as you wish.

DR. WALKER: This is one of the reasons. Another reason is that much of this information might be included under the next one, which is the preceptor statement, and considering the normal dose ranges and everything the individual would be working with.

This one was meant primarily for things that would be somewhat out of the ordinary, and a continuation sheet would be acceptable. Maybe we should explain that on the form itself, and I think that is a good point.

Maybe we should take comments for this first one before we go to the next one.

Dr. Holman?

DR. HOLMAN: Beginning with Supplement A, basically I was personally happy with the general concept. It was easy to read, it should be reasonably easy to fill out. But I have specific comments on Supplement A, type and length of training (d) and (e). You have broken it up into lecture/laboratory classes and a separate one for supervised laboratory experience. Why? For me it is very difficult to see what the difference is, and I think it would be extremely difficult for somebody who isn't familiar with the deliberations.

Is this information going to be used, i.e., a difference between those two categories? If not, wouldn't you be better off with one category?

The second issue has to do with quality, and I think you have come a long way by indicating that the applicant has successfully completed the program.

I would like to know a little bit more about the program supervisor and what his qualifications are. I would like to keep it simple. One possibility is to include the position of the program supervisor within the institution, whether he is full time, whether he is certified by other -- by various boards; but some type of indication of where his qualifications are.

FORM NRC-313M-SUPPLEMENT A U.S. NUCLEAR REGULATORY COMMISSION

(7)

TRAINING AND EXPERIENCE
AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF PROPOSED USER OR PROPOSED RADIATION SAFETY OFFICER	2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE (IF PHYSICIAN)

3. CERTIFICATION

SPECIALTY BOARD A	CATEGORY B	MONTH AND YEAR CERTIFIED C

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES
(To be completed by each institution providing training)

FIELD OF TRAINING A	LOCATION OF TRAINING B	DATE(S) OF TRAINING C	TYPE AND LENGTH OF TRAINING	
			LECTURE/ LABORATORY COURSES (Hours) D	SUPERVISED LABORATORY EXPERIENCE (Hours) E
a. RADIATION PHYSICS AND INSTRUMENTATION				
b. RADIATION PROTECTION				
c. MATHEMATICS PERTAINING TO THE USE AND MEASUREMENT OF RADIOACTIVITY				
d. RADIATION BIOLOGY				
e. RADIOPHARMACEUTICAL CHEMISTRY				

NAME OF PROGRAM SUPERVISOR CITY STATE ZIP

NAME OF INSTITUTION RADIOACTIVE LICENSE NO.

MAILING ADDRESS

I CERTIFY THAT THE INFORMATION PRESENTED ABOVE IS TRUE AND CORRECT TO THE BEST OF MY KNOWLEDGE AND BELIEF AND THAT THE APPLICANT SUCCESSFULLY COMPLETED THE PROGRAM.

DATE SIGNATURE OF PROGRAM SUPERVISOR*

*If the program supervisor is no longer available, then transcripts for the program signed by a representative of the institution or a certificate of successful completion signed by the program supervisor may be submitted.

WARNING-18 U.S.C., Section 1001, Act of June 25, 1948; 62 Stat, 749; makes it a criminal offe to make a willfully false statement or representation to any department or agency of the United States as to any matter within its jurisdiction.

5.(a) EXPERIENCE WITH RADIATION. (Actual use of Radioisotopes or Equivalent Experience)

ISOTOPE	MAXIMUM AMOUNT	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE

5.(b) EXPERIENCE WITH RADIOPHARMACEUTICAL PREPARATION
NUMBER INVOLVING PERSONAL PARTICIPATION

Mo-99/ Tc-99m	GENERATOR	
Sn-113/ In-113m	GENERATOR	
Tc-99m	REAGENT KITS	

NAME OF PROGRAM SUPERVISOR

NAME OF INSTITUTION

MAILING ADDRESS

CITY STATE ZIP

RADIOACTIVE MATERIALS LICENSE NO.

I CERTIFY THAT THE INFORMATION PRESENTED ABOVE IS TRUE AND CORRECT TO THE BEST OF MY KNOWLEDGE AND BELIEF AND THAT THE APPLICANT IS QUALIFIED TO INDEPENDENTLY PERFORM PROCEDURES UTILIZING THESE MATERIALS.

DATE

SIGNATURE OF PROGRAM SUPERVISOR

WARNING-18 U.S.C., Section 1001, Act of June 25, 1948, 62 Stat, 749, makes it a criminal offense to make a willfully false statement or representation to any department or agency of the United States as to any matter within its jurisdiction.

FORM NRC-313M-SUPPLEMENT 9 U.S. NUCLEAR REGULATORY COMMISSION

(8)

PRECEPTOR STATEMENT

(A separate form should be completed by each physician preceptor)

Supplement 9 must be completed by the applicant physician's preceptor. If more than one preceptor is necessary to document experience, obtain a separate statement from each.

1. APPLICANT PHYSICIAN'S NAME AND ADDRESS

FULL NAME

STREET ADDRESS

CITY | STATE | ZIP

KEY TO COLUMN C

PERSONAL PARTICIPATION SHOULD CONSIST OF:

1. Supervised examination of patients to determine the suitability for radioistope diagnosis and/or treatment and recommendation for prescribed dosage.

2. Collaboration in dose calibration and actual administration of dose to the patient including calculation of the radiation dose, related measurements and plotting of data.

3. Adequate period of training to enable physician to manage radioactive patients and follow patients through diagnosis and/or course of treatment.

2. CLINICAL DIAGNOSTIC TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS (Additional information or comments may be submitted in duplicate on separate sheets.) D
I-131 or I-125	DIAGNOSIS OF THYROID FUNCTION		
	DETERMINATION OF BLOOD AND BLOOD PLASMA VOLUME		
	LIVER FUNCTION STUDIES		
	FAT ABSORPTION STUDIES		
	KIDNEY FUNCTION STUDIES		
	IN VITRO STUDIES		
OTHER			
I-125	DETECTION OF THROMBOSIS		
I-131	THYROID IMAGING		
P-32	EYE TUMOR LOCALIZATION		
Se-75	PANCREAS IMAGING		
Yb-169	CISTERNOGRAPHY		
Xe-133	BLOOD FLOW STUDIES AND PULMONARY FUNCTION STUDIES		
OTHER			
Tc-99m	BRAIN IMAGING		
	CARDIAC IMAGING		
	THYROID IMAGING		
	SALIVARY GLAND IMAGING		
	BLOOD POOL IMAGING		
	PLACENTA LOCALIZATION		
	LIVER AND SPLEEN IMAGING		
	LUNG IMAGING		
	BONE IMAGING		
OTHER			

3. DATES AND TOTAL NUMBER OF HOURS RECEIVED IN CLINICAL DIAGNOSTIC RADIOISOTOPE TRAINING

PRECEPTOR STATEMENT (Continued)

4. CLINICAL RADIOPHARMACEUTICAL THERAPY TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN (Continued)

ISOTOPE A	CONDITIONS DIAGNOSED OR TREATED B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS (Additional information or comments may be submitted in duplicate on separate sheets D
P-32 (Soluble)	TREATMENT OF POLYCYTHEMIA VERA, LEUKEMIA, AND BONE METASTASES		
P-32 (Colloidal)	INTRACAVITARY TREATMENT		
	TREATMENT OF THYROID CARCINOMA		
I-131	TREATMENT OF HYPERTHYROIDISM		
Au-198	INTRACAVITARY TREATMENT		

5. DATES AND TOTAL NUMBER OF HOURS RECEIVED IN CLINICAL THERAPY RADIOISOTOPE TRAINING

6. CLINICAL TRAINING AND EXPERIENCE OF ABOVE NAMED PHYSICIAN USING SOURCES OR DEVICES FOR THERAPY

ISOTOPE A	TYPES OF TREATMENT B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	TOTAL OF TRAINING D	DATE(s) OF TRAINING E	COMMENTS (Append additional information, if necessary F
Co-60 or Cs-137	COURSES OF TELETHERAPY TREATMENT				
Co-60 or Cs-137	INTERSTITIAL TREATMENT				
	INTRACAVITARY TREATMENT				
I-125 or Ir-192	INTERSTITIAL TREATMENT				
Ra-226	INTRACAVITARY TREATMENT				
X-ray and Accelator Therapy	COURSES OF THERAPY TREATMENT				

7. THE TRAINING AND EXPERIENCE INDICATED ABOVE WAS OBTAINED UNDER THE SUPERVISION OF:

NAME OF SUPERVISOR

CITY STATE ZIP

NAME OF INSTITUTION

MATERIAL LICENSE NUMBER(S)

MAILING ADDRESS

I CERTIFY THAT (a) THE INFORMATION PRESENTED ABOVE IS TRUE AND CORRECT TO THE BEST OF MY KNOWLEDGE AND BELIEF AND (b) I WAS ALSO AUTHORIZED BY THE REFERENCED RADIOACTIVE MATERIALS LICENSE TO PERFORM THE PROCEDURES SPECIFIED ABOVE. I FURTHER BELIEVE THAT THE APPLICANT PHYSICIAN IS COMPETENT TO PERFORM THESE PROCEDURES INDEPENDENTLY.

DATE

PRECEPTOR'S SIGNATURE

WARNING-18 U.S.C., Section 1001, Act of June 25, 1948, 62 Stat 749; makes it a criminal offense to make a willfully false statement or

DR. WALKER: Both of these sound very reasonable, and this is a first draft, so I think this could be incorporated quite readily, and I think we will be discussing both of those suggestions.

DR. HOLMAN: One more quick comment. Under 5(b), generators are going to be playing an increasingly important role. It is going to be unclear which generators. Certainly molybdenum and technetium should be included.. The inclusion at this point of Sn-113 and Indium 113^m, I think this is used very seldom, but there may be other generators coming into practice, and I might suggest making line 2 "generator, other" and eliminate the Sn-113, but make it available for other generators that will be coming into use.

DR. WALKER: Thank you.

I think Capt. Briner has some comments along those lines.

CAPT. BRINER: I would question the Sn-113 and $In-113^M$ also, since to the best of my knowledge, there is no effective NDA for that in the United States.

DR. WALKER: That is correct.

MR. CUNNINGHAM: Dr. Workman?

DR. WORKMAN: When we previously met, we mentioned about a time requirement, that this training should be received in the past five years. Did you want to use that again, or --

DR. WALKER: Dr. Workman, we have been applying that

general principle ever since the last meeting. So since we do all these on a general case-by-case basis, we did accept your recommendation.

I think this is going to be explained in the new medical licensing guide, and I will see that every member of the committee gets a copy of this when it is published. I think you will find it very interesting.

Dr. Webster?

DR. WEBSTER: I think this idea of tightening up on the adherence to specific training requirements is probably more important than increasing the amount of clinical training as regards radiation safety.

Secondly, I would like to say that the name of the program supervisor may not be the teacher. Probably it will not be the teacher, in many situations, in most situations. And so I don't think we are getting at the point that Dr. Holman was raising, about the quality of the teaching. The program supervisor is likely to be the chief of nuclear medicine, for example, who did probably none of this teaching.

Of course, that may be in the radiopharmaceutical chemistry area.

DR. WALKER: Do you have any suggestions how to get around this? There may be a number of teachers within a given program.

DR. WEBSTER: Well, you probably won't get the

teacher specifically unless you have a separate category there. That might get a little unwieldy. It would have to be a separate entry, I think. It probably would cover the first four categories. I don't know how complicated you want to get. That's what inhibits me at this point.

(Pause.)

DR. WALKER: There has been one suggestion here made by another member of the Staff that we, instead of using the name of the program supervisor at this particular point, make it the name of the individual supervising the training in basic radioisotope handling techniques, which would cover especially what you said, and would at least make it an individual closer in the chain of command of responsibility.

DR. WEBSTER: I'll go along with that.

MR. CUNNINGHAM: Any other comments by our committee members on this portion of it?

If not, we will move right along.

What we will do with this, we are simply taking committee comments on the form itself. We will approve the form, but we are proceeding on the basis that we are going to some form like this that will be much tighter in substantiating qualifications to be licensed to use radioisotopes in medicine.

Would you like to proceed with the next one, Bill?

DR. WALKER: The next form has not changed as drastically as the first one. We tried to categorize things

so that we have broken down the clinical diagnostic training, the clinical radiopharmaceutical training and experience, and then the sealed sources and devices. This makes it a little bit clearer for people, where the old form did leave a little bit of doubt there.

We also asked more specifically for the same information that we expected to get on the other form, and we have made the statement by the preceptor a little bit clearer as to his responsibilities for stating this.

I will read just what it says in general, and this is, I think, the main part of the change. It says -- and this is the statement by the supervisor:

"I certify (a) that the information presented above is true and correct, to the best of my knowledge and belief; and (b) I was also authorized by the referenced radioactive materials license to perform the procedures specified above. I further believe that the applicant-physician is competent to perform these procedures independently."

Capt. Briner?

CAPT. BRINER: Under section 4, I would make the same comment about Au-198. While there is existing, or there are existing effective NDAs for that particular drug, in point of fact no one is marketing it in this country.

DR. ALMOND: I think Gold-198 seeds are not there for ~~intracavitary~~ treatment ~~specif~~ under 6.

DR. WALKER: Thank you. That's a good point.

DR. ALMOND: ~~And also~~ You should include in 6 interstitial use ~~specific as well as intracavitary~~.

DR. WALKER: Thank you.

Dr. Holman?

DR. HOLMAN: Again I think the basic concept is a good one. I feel that it means that this Supplement B, particularly section 2, particularly needs to be markedly up-dated. There is quite a bit -- quite a few procedures which are now done very little, and there should be added procedures which have now come into current use.

Specific recommendations I would make would be the inclusion of isotopes under Ag I-123 for thyroid procedures added to the 131 and 125. The deletion, I think, of selenium 75 pancreas imaging, which could come under other; similarly ytterbium 169, ~~cisternography~~ cisternography, replaced with indium 111 or added to other.

Under technetium 99m, I think cardiac imaging should be divided into subsets since they are different. One should be infarct, the other should be function studies. Placenta localization should come out, and kidney imaging should be added.

I think that in addition, under part 1, the key to column C, No. 1 and 2 are very good. They tell you specifically

what to do. Supervised examination of the patients to determine suitability of the patient for diagnosis, and two, collaboration and dose calibration and actual administration of dose. These imply that these will be done on each patient.

. Then we come to 3, and we talk about adequate period of training, and we lose the train of thought, which is that we are applying this to a number of cases rather than length of time, and I might simply change the wording in 3 to more accurately reflect that we will be looking at number of cases involved.

DR. WALKER: Thank you. When we are through, I would like to get the specific suggestions you made for changing the studies.

DR. HOLMAN: Also, is within your purview thallium-201 and gallium-67?

DR. WALKER: These are not, but the experience gained by using some of these might be important in evaluating a physician's training and experience.

MR. CUNNINGHAM: Dr. Griem?

DR. GRIEM: Yes. Under 6, there are several training programs in the city of Chicago in which there are no more cobalt therapy units, but there may be some accelerators. Now the person will be certified as having adequate experience with accelerator therapy, and moves out to a small town where there is just a cobalt machine, and I wondered how the Staff handles that problem.

DR. WALKER: I'm not quite sure I understand.

DR. GRIEM: Well, I have a hospital on the near South Side that is not ours, and they have two accelerators, and they certainly train people adequately in radiation oncology.

Now one of these people would go out to Peoria, where there is a cobalt machine and that's all. Now the person has had no experience that you can write down there on the cobalt, yet he has certainly had three years of training in radiation, which is equivalent to --

MR. CUNNINGHAM: Your question is quite simple. How can he take credit for use of accelerator and cobalt teletherapy? We haven't considered this question. I don't know if it's a big issue or not, but it is something that we need some -- I think we have to explore the issues, and perhaps come back to the committee on how we take credit for that.

I believe that specific type of example would be one that we would handle on a case-by-case basis, because I really don't think it is going to be a type of situation where we would get a large volume of cases.

Any other comments on the form? Dr. Collins.

DR. COLLINS: I couldn't hear. Did Dr. Almond suggest we move under interstitial treatment and include Au-198?

DR. ALMOND: Yes.

MR. CUNNINGHAM: I believe that's correct.

If there are no more comments on the form, I believe

we can move on to the next item.

Let's check our time here. It is now five minutes past 12:00.

(Pause.)

I think it would be a good idea if we tried to break at this time and come back to consider the remainder of the agenda. Some of you are staying at this hotel and will want to check out before the 1:00 o'clock deadline. It is now 10 minutes after 12:00.

I would like to resume the meeting at 1:15 promptly. We will try to adjourn the meeting some time between 3:00 and 4:00 o'clock, for those of you who have planes to get.

Before we do break up, though, I want to just briefly discuss a rule change that the Staff currently has under consideration, because we are going to receive comments on it from not only the committee, but members of the public.

I believe, as many of you know, in biomedical research, we have two categories of waste that are presenting a large volume and presenting special problems. They are the ~~simulation~~ scintillation vials containing organics, toluene and so forth, that will be used in ~~simulation~~ liquid scintillation counting, containing small quantities of largely tritium or carbon-14.

We also have a problem with disposing of items with again small traces also of tritium and carbon-14. We are considering a rule change that has not yet been ~~sent~~ sent to the

Commission. The Staff is currently hard at work drafting such a rule, which would essentially remove from NRC regulatory control scintillation fluids and animals with tritium and carbon contained in them, below a certain concentration.

We are selecting 0.05 microcuries per gram as the cut-off point. This, in effect, would release these materials from regulatory control, so they could be disposed of as if they were -- did not contain radioactive materials. This would take a lot of pressure off biomedical research institutions, and it would be helpful to the budget to take a lot of pressure off, as we believe both of these are small.

Shortly after lunch, I will review with you more specifically what we propose to do, what the anticipated radiological impacts are, what the anticipated benefits are, because we are trying to move fairly rapidly on this matter.

I will seek some opinion from the committee on whether or not this rule is justified and beneficial, on the assumption that the Staff analysis of the quantities of materials involved and the calculations are correct. I do not ask the committee to take a position on that, to justify calculations. To the extent that those of you in the audience represent professional organizations like Society of Nuclear Medicine and other groups, I would also like some statement from you after I get through explaining what the Staff proposes to do, as to whether or not it is justified and would be helpful to the medical community

and biomedical research. So you might be thinking about that during the lunch break.

I would ask that you be back here at 1:15 promptly.

Thank you.

(Whereupon, at 12:12 p.m., the meeting was recessed, to reconvene at 1:15 p.m., this same day.)

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AFTERNOON SESSION

(1:35 p.m.)

MR. CUNNINGHAM: May I have your attention, please? We are going to reconvene the meeting.

When we broke just before lunch, we completed three of the four agenda items on training. We have two more agenda items following this.

The last agenda item on training has to do with acceptance of board certification as evidence of adequate training. We have one or two people who wish to speak on the subject.

First on my list is Dr. George Faerber and the American Osteopathic College of Radiology. Dr. Faerber, do you want to make a statement?

Again, for those who are making statements, I ask that you limit your summary to five minutes, and the full statement will be included in the transcript.

DR. FAERBER: Thank you. I think maybe my statement will be a little bit shorter than it might have been earlier this morning, since the sands have been shifting a little bit.

I am George F. Faerber, D.O., an osteopathic physician practicing radiology and nuclear medicine in Columbus, Ohio. I am pleased to represent the American Osteopathic College of Radiology before the Advisory Committee. I am currently the Vice President of the American Osteopathic College

of Radiology. I am Chairman of the Committee on Continuing Post-Graduate Education. Also here to answer any questions that you may have are Manuel Sloane, D.O., the president of the AOCR, William Lavendusky, D.O., past president of the AOCR, also a member of the board of Osteopathic -- American Osteopathic Board of Radiology; George Gustafson, D.O., who is in radiation and oncology, Detroit, Michigan, in Detroit Osteopathic Hospital; and Richard DiPietro, who practices nuclear medicine in York, Pennsylvania.

Drs. Sloane, Lavendusky, DiPietro and I also hold the certificate of the American Board of Nuclear Medicine.

In the Federal Register of June 25, 1980, the question is stated, should certification by the osteopathic boards be accepted for licensing purposes in the same manner as their counterparts, the ABR and the ABMM.

Actually the American Osteopathic Board's certification of radiology was accepted either fully or partially up until 1978 for qualification in teletherapy. In 1977-78, as the American Board of Radiology was phasing out their general radiology certificate programs, the Advisory Committee began to reevaluate our board's acceptance.

Unfortunately, at that time, due to out-of-date information, which was sent to Dr. Leo Wade by the American Osteopathic Association, the Advisory Committee in 1977-78 evaluated our minimum standards for state training as of 1968,

when, in fact, we were operating under a set of standards revised in 1975.

Since that time, our categories of certification have also been realigned into diagnostic radiology, that was 1980, and radiation oncology, 1979. That was a new revision of previous minimal standards in radiation therapy.

However, we have still retained certification in radiology. The minimal standards for these categories which were drafted by the American Osteopathic College of Radiology and accepted by the American Osteopathic Association, have previously been submitted to your board for evaluation.

As you probably can see by the material which has been submitted, our certificates and our present minimal standards are not exact coordinates of those of the ABR.

For instance, our diagnostic radiology residency, which requires three years of training in radiological sciences, after one year of internship, requires a minimum of three months in nuclear medicine and sufficient training in basic radioisotope handling techniques qualified for NRC licensure.

Now, in most cases, these 200 hours of training are given separately from the three-month -- a minimal three-month rotation through nuclear medicine. Our radiology program requires after one year of internship, three years of study in the radiological sciences, including three months in radiation therapy, as far as an introduction to this field, and three

months in nuclear medicine, with sufficient training in basic radioisotope handling techniques to qualify for an NRC licensure. The radiation oncology program requires three full years of training in radiation therapy following one year of rotating internship.

This includes at least 200 hours of training in basic radioisotope handling techniques. All of our residency programs are reviewed and inspected by the Committee on Education and Evaluation of the American Osteopathic College of Radiology and by the Committee on Post-Graduate Training of the American Osteopathic Association.

After a candidate has completed one of these training programs, he is examined by the American Osteopathic Board of Radiology, which is the agency of the American Osteopathic Association recognized by many federal agencies for certification of osteopathic physicians in radiology.

In summary, we would like the NRC to accept the American Osteopathic Board of Radiology certificates on the basis of the material contained in our programs, as documented by the minimal standards which have been submitted to the committees; on this basis, we propose that our certificate should be accepted for the following groups:

Diagnostic radiology, Groups I, II and III.

Radiology, Groups I, II, III and IV.

Radiation oncology, Groups V, VI, and teletherapy.

That completes my presentation. If there are any questions, either I or my colleagues will be happy to answer them.

MR. CUNNINGHAM: Thank you very much, Dr. Faerber.

Are there questions from members of the committee? Dr. Holman?

DR. HOLMAN: It's more than a question. In January at the committee meeting, I was concerned, and the American Board of Nuclear Medicine presented a proposal for the use of the certification for therapeutic applications, and my concern at that time was not on content, but on information available to me to make a decision.

The same applies here. I really don't have enough information provided to me concerning the examination itself, the types of questions that are being asked, and nuclear medicine procedures. In particular, the safe handling of radio tracers, and some index of the competence of individuals who are passing the examination, to permit me to make a decision in terms of the decision on whether this board should be sufficient mechanism for certification.

So what I would request -- and I am not sure that it could be made available to me now -- but what I need to make this decision, have an idea what the examination is, what its contents are, and additional information concerning the examination itself, in addition to the information you have already

provided us, in terms of the residency training program.

DR. FAERBER: I believe Mr. Camper of the NRC has communicated with Dr. Betts, who is the president of the American Osteopathic Board of Radiology regarding the types of questions, whether they cover radiation detection and that sort of thing. I am not sure if you have that information. Has that been returned to you?

(Discussion off the record.)

MR. CUNNINGHAM: I guess the answer to the question is, that some information was mailed to Mr. Camper, but not the information that is suggested. They said they will send it to us. Perhaps they haven't had a chance to get together on it. Is there assessment of where we stand, Larry?

MR. CAMPER: Particularly Groups IV and V.

MR. CUNNINGHAM: Groups IV and V. Now I don't know, Larry, perhaps you can expand on this. Have we requested the information as outlined by Dr. Holman?

This is Larry Camper, a member of our Medical Licensing Staff.

MR. CAMPER: Yes, we did request information relevant to their training and testing criteria and so forth. We have received a substantial packet of information which is enclosed.

The group has indicated to us that they will be forwarding information on to the therapeutic procedures, particularly Groups IV and V. Once they have a chance to

obtain a consensus from their board of examiners. It was lack of time to provide us with all the information to all the therapy.

However, they have provided substantial information to the diagnostic groups and to the training for the residency programs, and so forth.

DR. HOLMAN: Yes, to training, but not the examination itself, which is what we are being asked to make a decision upon.

MR. CAMPER: That is correct. There was a concern, as I recall, relative to the security of the test in terms of putting forth specific test questions, criteria, and so forth.

Therefore, I think they said they would provide as best they could information without violating the security of the examination.

MR. CUNNINGHAM: Dr. Faerber, how do we get around this problem? Apparently you have a problem with the security of your examination that has to be weighed against the question of our ability to assess the quality of the people that pass this examination.

DR. FAERBER: Could I ask other than perhaps some of the members here that have taken some other examinations, is that a common procedure, to review all the questions, say from the Board of Nuclear Medicine or the Board of Radiology?

In other words, we are the federally recognized examining agency for osteopathic physicians in this area of radiology. So if it is common practice to provide all the

questions from other boards, then certainly as osteopaths, we would provide our questions.

DR. HOLMAN: Well, the point that I raised in January was just this, that there needs to be a uniform approach to the evaluation of these examinations. I certainly did not intend my question in any way to imply that there would be a different standard applied to your examination as to others. But I think that just as I raised the objection to the American Board of Nuclear Medicine in January, they therefore came back at this meeting with more extensive exposition of their case.

I think the same thing is true here. We simply have no basis on which to judge the content of the examination. I think it can be done in ways other than providing us with the examination itself, but there must be some mechanisms for us to form an opinion.

DR. FAERBER: Yes, I think the approach was the percentage of questions applying to various aspects of radiation protection, dosimetry was being accumulated. That was a relatively recent request, I think in the end of July or something. So it was really difficult to make sure that we had every board member polled on his part of the examination.

But Dr. Lavendusky is here, who is a member of the Board of Radiology, and if he can illuminate any specific questions.

MR. CUNNINGHAM: Well, is it an issue-specific

question? The questions that are being asked are really the quality of -- what you're trying to get to is the quality of the person after they have passed. This is the problem which faces Dr. Holman, as he pointed out, with the Board of Nuclear Medicine, I suppose, to some extent, and applies to various radiology boards. But not all of them, certainly.

And I can ask Dr. Christie, certainly, he wanted to make a statement there. If I can ask you to yield just a moment, Dr. Faerber, on this specific issue.

DR. CHRISTIE: I think the important consideration here is not -- is the fact that you are only accepting, as far as I know, a special competence certificate carte blanche, which is a year's training, and unless we can reasonably guarantee that these people have had adequate training. However, the three months, we are talking about minimum training, at most, and probably after today it will not even be minimum training.

Therefore, we have not asked and will not ask that you accept our three-month people carte blanche.

MR. CUNNINGHAM: Thank you, Dr. Christie.

DR. FAERBER: I might point out there is only one other category, that's diagnostic radiology, that requires a minimum, which up until this morning or until the actual ruling comes out, is the minimal standard. In our programs, as in any integrated radiology program, they are dealing with radiation effects, radiation biology, radiation images during the whole

program. The minimum of three months in the radiology residency is a little different than a minimum of three months in internal medicine or cardiology.

MR. CUNNINGHAM: Does any other member of the committee have questions of Dr. Faerber?

DR. WEBSTER: I have some questions.

MR. CUNNINGHAM: Yes, Dr. Webster.

DR. WEBSTER: Essentially along the lines of Dr. Holman. I have questions essentially along the lines of Dr. Holman's questions.

I received a substantial package of material, along with everybody else, and I reviewed them rather carefully. It seems to me that only in one area, namely radiation oncology, was there a specification of the amount of training in basic radiological handling techniques, where indeed there was the 200-hour figure. In both radiology programs and the diagnostic radiology programs, there was no such specification, and so it was very hard to judge how much training in these basic areas was being given.

Also attached to these programs were a couple of short courses given by Mr. Fields and Mr. Griffiths. I don't know whether you were holding these out as typical of the training programs in radiation physics, but they were all together about 20 hours of training, 15 hours in physics and instrumentation, and four hours in radiation safety.

My judgment on that would be that would be quite inadequate to meet this Commission's ground rules.

The other point that struck me was that only in one area was it specified that the training program should have a full-time radiation physicist in it, and that was in radiation oncology, and so the question does arise, who is teaching the basic handling techniques in diagnostic radiology and indeed nuclear medicine?

I couldn't find any of those answers in the documents submitted.

DR. FAERBER: I'll take the first question first. Regarding the minimum number of hours in basic radioisotope handling, there is a clause in there that states that the residency shall comply with the minimum number of hours required by the NRC.

Now you probably can realize that this has been changing over the past three, four or five years, quite rapidly, or six years; and it takes some time for our minimal standards to be presented from the college to the committee of the American Osteopathic Association. And then it has to be approved by that board.

So the statement was they will meet that requirement.

The second question regarding some examples of an accessory course, essentially that was put on by the college as part of the continuing post-graduate education program. That

is not meant to be the only or the sole course in radiation physics.

It so happens the ~~program~~ chairman of each program makes the decision on which physics program will be adequate for his residents in training, meeting the requirements of at least the 200 hours for the basic handling permit.

That may be courses at an adjacent or nearby university which has a program ongoing; it may be given by the local radiation physicist, whether he be full time or part time. I am not sure that that necessarily is pertinent for how much he devotes to the training program.

So that that course per se was only a fragmentary submission. In effect, the course continues every year. The didactic 24 hours of review. And you probably didn't have the complete cycle of courses.

In addition, there is a described program for hospital study before the candidates would attend that course. But that is not meant to be the only course.

DR. WEBSTER: Can I come back just a little bit? I'm reading now from the educational program minimum basic science requisites. It says that the program in nuclear medicine shall be three months. It shall offer appropriate training in physics, instrumentation, radiopharmacology, radiation protection, interpretation of nuclear studies. But it doesn't actually break it down.

It does say, however, that it is recommended that the program qualify the resident for licensure. However, that is a recommendation that presumably is not mandatory, and I have some doubts about whether indeed many of your programs would meet the current requirements.

It is recommended, but it should be stronger than that.

DR. FAERBER: This is the diagnostic radiology?

DR. WEBSTER: Yes. And the same thing is true -- no, this is radiology. They are almost identical wordings on radiology and diagnostic radiology.

DR. FAERBER: Well, as you are aware, it is extremely difficult to be specific in every regard of training. I'm not sure that any other organizations are extremely specific in that regard, either. It is a matter of acceptance of the board and its trainers and its programs. So that that would be a difficult problem to overcome, if you have some basic feeling that you don't have enough information. Because I am not just sure that it's really available from any board, extremely specific documentad form.

DR. WEBSTER: The thing is, in radiation oncology, more specific, you did put down 200 hours, and that's what sort of flashed out at me, that you hadn't done it anywhere else. But again I come back to the point that it is hard to arrive at some kind of an evaluation from what is given here, particularly

when you do present programs which -- as examples which didn't appear to me quite adequate. These were addenda to these documents.

MR. CUNNINGHAM: Any other questions of Dr. Faerber? We still have-- thank you very much, Doctor.

(The statement follows:)

DCMS

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BETTS RADIOLOGICAL ASSOCIATES
1176 CLARK STREET
LANCASTER, PENNSYLVANIA 17604

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RECEIVED

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July 24, 1980

...TION

Mr. Larry Camper
U.S. Nuclear Regulatory Commission
Box 396 SS
Silver Springs, MD 20910

Dear Mr. Camper:

This letter will serve to confirm our recent telephone conversation regarding the desire of recognition of certification by the American Osteopathic Association of Radiologists by the Nuclear Regulatory Commission for appropriate categories of groups of nuclear material.

As explained to you on the phone, the American Osteopathic Board of Radiology examines individuals in appropriate categories prechosen by the candidate depending upon his educational credentials which are verified by the Secretary of the Board before the individual is admitted to the examination. The actual requirement of training is not a function of the Board but of the College, and, as I understand it, you have received other information dealing with minimal standards from another source.

The actual examination covers both written and oral exams in the following areas: 1) Radiation biology, 2) Radiation physics, 3) roentgen technique, 4) principles of roentgen diagnosis and diagnosis of neoplasms, 5) roentgen therapeutics to include radium and radium substitutes, 6) nuclear medicine. The basic format is multiple choice, fill-in or true-false with few essay types. The exam takes four full days of the candidates time with eight to five and additional time requirements if needed for a given candidate.

We will have to survey the various examiners of the Board to receive answers to the percentage of questions dealing with isotope therapy, dosage, target organs, safety, patient handling, precaution, decontamination procedures and indications for treatment. I am sure you can appreciate my inability to give definite numbers at this time. The Secretary of the Board has been contacted and will attempt to accumulate this data from the other members of the Board of Examiners as soon as possible.

Unfortunately, due to prior commitment, I will not be available for the meeting on 18 August. I would hope someone representing the Board will be able to communicate any information I receive or have it available at the meeting on the 18th of August.

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INSPECTION AND ENFORCEMENT

If there is any additional information you may require, do not hesitate to contact me either by mail or phone.

Thank you in advance for your attention to this matter.

Sincerely yours,

William E. Betts, Jr., D.O.
Chairman, American Osteopathic
Board of Radiology.

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AMERICAN OSTEOPATHIC COLLEGE OF RADIOLOGY

RECEIVED

May 28, 1980

PRESIDENT
MANUEL SLOANE, D. O.
SPROUL ROAD & THOMSON RD.
SPRINGFIELD, PA 19064

Dr. William Walker
Material Licensing Branch
Nuclear Regulatory Commission
Washington, D. C. 20555

Dear Dr. Walker:

Thank you for verifying the meeting date with you in Washington on Monday, June 9th at 1:00 P.M., as per our phone conversation today. The purpose of such meeting will be to identify any misunderstanding or misinformation on the part of the American Osteopathic College of Radiology, the American Osteopathic Board of Radiology and the NRC as related to licensing for teletherapy and brachytherapy sources.

It may well be that there has been no official response from the American Osteopathic Association or the American Osteopathic College of Radiology to the letter dated February 6, 1978 to Dr. Crowell from Dr. Wade. Almost two and a half years have gone by and I agree with you that this preliminary meeting is the most direct way to begin to clarify this matter.

Scheduled to represent our profession at the June 9th meeting will be Robert L. Meals, D.O., Professor and Chairman of the Department of Radiology, Hospital of the Philadelphia College of Osteopathic Medicine, member of the American Osteopathic Board of Radiology; George Faerber, D.O., radiologist, Doctors Hospital, Columbus, Ohio, Vice President, American Osteopathic College of Radiology; George Gustavson, D.O., Director, Radiation Oncology, Detroit Osteopathic Hospital, Detroit, Michigan; and Richard DiPietro, D.O., radiologist and Director, Department of Nuclear Medicine, Memorial Osteopathic Hospital, York, Pennsylvania.

Under separate cover, I am sending current AOA approved Minimal Standards for Residency Training in Radiology, Diagnostic Radiology, and Radiation Oncology.

Thank you again for your cooperation in arranging this meeting.

Sincerely yours,

Manuel H. Sloane, D.O.
President, AOCR

ATTACHMENT NO. 4

cc: Mrs. Patricia Vacca
Mr. Richard Cunningham
Edward P. Crowell, D.O.
Mrs. Pam Smith

AMERICAN OSTEOPATHIC COLLEGE OF RADIOLOGY

215-323-4260

PRESIDENT
MANUEL SLOANE, D.O.
SPROUL ROAD & THOMSON RD.
SPRINGFIELD, PA 19064

June 28, 1980

Richard Cunningham, Ph.D.
Chairman
Advisory Committee on Medical Uses of Isotopes
Division of Fuel Cycle and Materials Safety
Nuclear Regulatory Commission
Washington, D.C. 20555

Dear Dr. Cunningham:

I would like to express my appreciation to Dr. William Walker and Mrs. Pat Vacca who arranged the meeting with members of the American Osteopathic College of Radiology on June 9th in Washington. All the members of our group were most pleased with the courtesies extended and the explanation of current NRC policies and procedures with regard to brachytherapy and teletherapy licensing and materials handling licensure as this pertains to nuclear medicine uses.

As you may know, osteopathic radiologists are responsible for nuclear medicine services in over 200 osteopathic hospitals. The large majority of these institutions have AOA-approved intern and residency training programs, and many have active departments of radiation oncology. Moreover, the AOCR provides radiology faculty for the 15 colleges of osteopathic medicine. Therefore, we strongly feel that it is important from both an informational and educational standpoint to have a member of our College appointed to the Advisory Committee on the Medical Uses of Isotopes. We understand that there is no vacancy at the present time. However, when such vacancy does occur, I would like to propose appointment be considered of one of the following radiologists in order of preference as listed:

(1) Dean Fullingim, D.O.
Department of Nuclear Medicine
Oklahoma Osteopathic Hospital

(2) Richard DiPietro, D.O., Director
Department of Nuclear Medicine
York Memorial Hospital

(3) George Faerber, D.O.
Doctors Hospital
Columbus, Ohio

ATTACHMENT NO. 4

A curriculum vitae will be submitted under separate cover by Mrs. Pamela Smith, Executive Secretary, AOCR. It might be best to address all requests for information to Mrs. Smith.

It is my understanding that the agenda of the Medical Advisory Committee meeting will take up the topic of recognition of certification boards at the August 18th meeting. In this regard, we would like to request the following:

(a) Certification by the American Osteopathic Board of Radiology (AOBR/Diagnostic Radiology be automatically recognized by NRC for licensure for Groups I, II, and III.

(b) Certification by AOBR/Radiology be automatically approved for licensure Groups I, II, III and IV.

(c) AOBR/Radiation Oncology Groups V and VI.

(d) American Osteopathic Board of Nuclear Medicine (AOBNM) - Groups I, II, III, and IV.

I will forward to you, under separate cover, the currently approved AOA Minimal Standards for Residency Training in Diagnostic Radiology, Radiology and Radiation Oncology Also to be included will be descriptive physics course material sponsored by the AOCR during the past year.

There are probably several other areas where you may need information as to structure and inspection of the residency program, their relationship to the AOA, the American Osteopathic Board of Radiology, and the Committee on Postdoctoral Training and the Bureau of Education of the AOA. I will forward a copy of our inspector's manual with a covering letter relating to our inspection procedures as carried out by the Committee on Evaluation and Educational standards.

I will call you in approximately one week in order to facilitate sending additional information that you may deem necessary.

Sincerely yours,

Manuel H. Sloane, D.O.
President, AOCR

ATTACHMENT NO. 4

MHS:ff

cc: William J.Walker, Jr., Ph.D.
Mrs. Patricia Vacca
Mrs. Pamela Smith, Executive Secretary
American Osteopathic College of Radiology
Route 2, Box 75
Milan, MO 63556
Mr. D. Nussbaumer
Mr. V. L. Miller

AOCR

ERICAN
EOPATHIC
COLLEGE OF
RADIOLOGY

LA A. SMITH
EXECUTIVE SECRETARY

ROUTE 2, BOX 75
MILAN, MO 63556

(816) 265-4951

July 9, 1980

Ms. Pat Vacca
Section Leader
Medical Licensing
Division of Fuel Cycle and
Materials Safety
Nuclear Regulatory Commission
Washington, D.C. 20555

Dear Ms. Vacca

Mr. Cunningham has requested that we send additional information relating to our residency training program to your attention. I am enclosing the following:

Basic Standards for Residency Training in Radiology
Basic Standards for Residency Training in Diagnostic Radiology
Basic Requirements/Minimal Standards for Residency Training in Radiation Oncology
Procedure of "How to Initiate a Residency"
Inspection Report Form
Continuing Medical Education Programs
The Physics of Nuclear Medicine
The Physics of Diagnostic Radiology
The Physics of Therapeutic Nuclear Medicine and Radiology
Six-Month Study Program correlating with the CME course,
The Physics of Diagnostic Radiology

A six-month study program is correlated with each of the Physics Programs. The study program for the 1981 program, The Physics of Therapeutic Nuclear Medicine and Radiology is at the printer at this time and will be forwarded to you at a later date.

If you desire further information, please do not hesitate to contact me.

Sincerely

Pamela A. Smith
Executive Secretary

cc Dr. William Walker
Mr. Richard Cunningham
Dr. Manuel H. Sloane
Dr. Edward P. Arrowell

AMERICAN OSTEOPATHIC COLLEGE OF RADIOLOGY

RECEIVED

JUL 13

PRESIDENT
SAMUEL SLOANE, D. O.
PROUL ROAD & THOMSON RD.
SPRINGFIELD, PA 19064

July 17, 1980

Mrs. Patricia Vacca
Section Leader
Materials Licensing Branch
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Dear Mrs. Vacca:

The minimal standards for residency training in radiology, diagnostic radiology, and radiation oncology sent to you by Mrs. Pam Smith, Executive Secretary, AOCR, unfortunately were draft copies. The AOA-approved copies will be forwarded immediately.

The following is an overview of radiology residency programs as to method of origin, program approval, training, program inspection, and the relationship between the American Osteopathic College of Radiology (AOCR) and the American Osteopathic Board of Radiology (AOBR).

The hospital must first request approval for a residency program from the Office of Education of the AOA. The Office, if after reviewing the submitted documents and information submitted, finds same in compliance, will request the Evaluation and Educational Standards Committee (EESC) of the AOCR to conduct an inspection of the program. (See inspection report form mailed to your office 7/9/80). The chairman of the EESC will assign a junior and senior inspector to conduct an on site inspection and send the report to the Office of Education of the AOA. The report is then discussed by the EESC and the resulting recommendation of approval for one to three years or disapproval with appropriate documentation is forwarded to AOCR Board of Directors for appropriate action. The recommendation of the AOCR Board is then forwarded to the AOA Office of Education. Such recommendation is then approved or denied by the Committee on Post Doctoral Training (COPT). The COPT actions are then placed on the Agenda of the next AOA Board of Trustees' semi-annual meeting for final approval or denial. All requests for additional residents go through the same process. Hospitals which are denied programs have the opportunity for remedy through an appeals process.

ATTACHMENT NO. 4

In radiology and diagnostic radiology residency programs the EESC requires that the nuclear medicine portion of the program be a minimum of three months block time which is sometimes necessary if the nuclear medicine section is under the Department of Pathology or Internal Medicine, or the program director prefers to send the resident out of the hospital for a better educational experience. The resident is to apply for materials handling license upon completion of his nuclear medicine training and preferably his name added to the hospital NRC license. In this manner, there is demonstrable proof of fulfillment of NRC requirements for licensure. If application is not made, then the trainor and the resident are required to document the educational experience in detail in keeping with NRC requirements (see enclosed VIEWBOX articles, Oct. 1978 and Dec. 1979, an official publication of AOCR). All radiology residency programs which have osteopathic physicians who wish to be eligible to take the AOBR certifying examination are inspected on site every three years. This includes any military, public health or allopathic hospital. The inspection process is identical.

The American Osteopathic Board of Radiology (AOBR) is independent of the AOCR, except that members of the AOCR are nominated by the AOCR Board and, subsequently, elected by the College membership for appointment to the AOBR as vacancies arise. The AOBR is responsible for setting its own criteria for oral and written examination and examines twice yearly. The AOBR has the option of appointing radiological physicists or osteopathic physicians certified in radiology for positions as supplementary examiners based on their expertise and experience as the need may arise. The AOBR does not set the residency standards. It only examines candidates eligible for certification. Candidates who successfully pass the Boards are recommended to the AOA Board of Trustees for ultimate certification. I believe Dr. Crowell, in his letter of November 18, 1977, sent Dr. Wade information re: "Requirements for Certification of the Advisory Board for Osteopathic Specialists and Boards of Certification".

At best, the above is only a summary and I would appreciate any specific questions requiring more detailed explanation prior to the 8/18 meeting of the ACMUI.

Thank you in advance for your cooperation.

Sincerely yours,

Manuel H. Sloane, D.O.
President, AOCR

ATTACHMENT NO. 4

MHS:FF
cc: Dr. William Walker
Edward P. Crowell, D.O.
William L. Lavendusky, Jr., D.O.

AOCR President Reports on Past Year

(Continued from page 1)

support in order to be successful. I would urge everyone to take part in this extremely worthwhile educational effort.

In memorandum to "The Advisory Board for Osteopathic Specialists," Dr. Donald Sieht, A. O. A. President, makes the following statement: "During the coming year, I also would ask the Board to seriously consider the possibility of implementing recertification on a voluntary basis by 1981. I believe recertification for osteopathic specialists might be best accomplished on a clinical review or peer review basis, rather than through C.M.E. or a written examination. Patient examination or oral examination might be most effective in some specialities." I feel that the matter of re-certification is of great importance to our membership and that we should convey our feelings on this issue to Dr. Sieht.

Now is the time for Radiologists who have been certified by the American Osteopathic Board of Nuclear Medicine to become charter members of the new Osteopathic College of Nuclear Medicine. This would in no way conflict with present membership in the American Osteopathic College of Radiology.

Another item which is currently under consideration by the Board of Directors should also be the topic of discussion at the annual business meeting. We are investigating the feasibility of employing a full or part-time Executive Director for the American Osteopathic College of Radiology. Dr. Willman will present a report to the Board of Directors at the annual meeting on this matter. This concept presents both advantages and disadvantages for the College and should be thoroughly discussed by the general membership in Atlanta.

The American Osteopathic College of Radiology has been a progressive, successful organization because of the active loyal support of the general membership. As the outgoing President, I want to express my appreciation to our members for making our College function so well. I consider it a great honor to have had the opportunity to be President of such an excellent organization. Thank you all.

Fraternally yours,
Arthur Simon, D.O.
President, American Osteopathic College of Radiology

Need Evaluated

As stated in the President's report, one of the most important items on the agenda will be a discussion by the Board of Directors with subsequent recommendations for action by the membership regarding the needs, objectives, and job duties and requirements of an Executive Director to assist in the day-to-day conduct of the vital activities of our College. As our organization grows in membership, budget expenditures, so do the number and complexity of day-to-day tasks that must be discharged by the officers, board of directors, and committee chairmen of our College. A careful analysis of these tasks are being prepared by Dr. Willman and his committee as part of the agenda of the board of directors' meeting. The results of such discussion, we trust, will be constructive and in the best interest for the continued growth of our College and the fulfillment of our objectives. Now is the time to consider the advantages to our College of an Execuive Director.

VIEWBOX

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Nuclear Medicine Upgrade

The agenda of the Atlanta meeting of the Committee on Evaluation and Educational Standards headed by Dr. Joseph Andrews will contain a proposal to upgrade the minimal nuclear medicine standards for residency training in the radiological sciences. The proposal requires that the clinical training and documented experience of the resident will endeavor to qualify the resident for Nuclear Regulatory Commission (NRC), materials handling licensure. At the present time this is recommended but not mandatory.

The hours of training now required by the NRC could be compressed into the 3 months now allotted to training in nuclear medicine but this exposure whether within or outside the institution would of necessity be concentrated with appropriate documentation on actual NRC licensure forms by the physician responsible for the nuclear medicine training to be included in the program directors annual report and in the residents' records.

Upon completion of training and taking a position as a staff radiologist, this training record would be readily available for promptly processing a materials handling license. Even if nuclear medicine were not part of the radiology department, the radiologists name on the hospital license albeit with consent of the director of nuclear medicine services could result in valuable back up for the hospital in event of vacation, illness, or emergency.

There are several benefits to the resident. Of primary importance is the ability to qualify for radiology positions that require performance of nuclear medicine procedures. Under existing Federal Regulations such procedures can only be carried out or supervised, if the physician is named on the hospital license. Second, licensure is a prerequisite for certification by the American Osteopathic College of Nuclear Medicine. Third, but no less important is the medicolegal aspect. A radiologist and or hospital could be adversely implicated if in a medicolegal claim concerning a nuclear medicine procedure, it was determined that the radiologist involved was not licensed to handle the radioactive nuclide used.

The major disadvantages to this proposal are that the NRC is continually raising the requirements for licensure and the 3 year residency program in radiology is being subjected to pressures requiring inclusion of newer diagnostic modalities such as ultrasound and CT. Three years is getting to be a shorter and shorter time span in which to train a radiologist. Thus the importance of our college encouraging improved programs and recruiting better candidates.

Manuel H. Sloane, D.O.

Preparing For An Inspection Of The Residency Program

The Radiologists, Director of Medical Education and the Hospital Administrator should be familiar with Residency Training Program requirements. The following publications should be carefully studied and followed: "Requirements and Interpretative Guide for Hospitals Accredited and Approved for Intern and/or Residency Training by the American Osteopathic Association;" Minimal Standards and Requirements for Specialty Training in Radiological Science – Committee on Postdoctoral Training, American Osteopathic Association and Evaluating Committee, American Osteopathic College of Radiology;" and "Hospital Requirements for Residency Training in Osteopathic Specialties."

Copies of these documents are available from the Office of Hospital Affairs, American Osteopathic Association, 212 East Ohio Street, Chicago, Illinois 60611.

Evidence of compliance with all requirements should be documented and available for the inspector including: Copy of Updated Residency Training Program; Reading Assignments; Resident's Log; Monthly Statistics of Exams Done (Type and number); Latest Department Radiation Survey; Film Badge Reports; Bedside Training; In-Hospital Lectures; Minutes of meetings, including committee, staff and decartmental meetings; Documentation of attendance; Autopsies; Conventions; Post graduate courses for the trainee and trainer; Medical records of representative cases; Representative roentgen studies, Radiation Therapy cases and Nuclear Medicine cases; Pathology gross file; Therapy and Radium records; and Nuclear Medicine records.

The Department Head, as well as the assistant trainers, residents, head technician, Director of Medical Education and Hospital Administrator, should be available for interview.

Membership records of the Radiologist trainer or trainers in the American Osteopathic College of Radiology should be available.

The Director of Medical Education should have available the lecture and teaching program of the hospital for interns, residents, and staff and record of participation and attendance of the Radiologists and Residents.

The Hospital Administrator should have the statistics for hospital admissions, surgeries, pediatrics, orthopedics, O.B., medicine, radiology, radiation therapy and nuclear medicine, autopsies, etc.

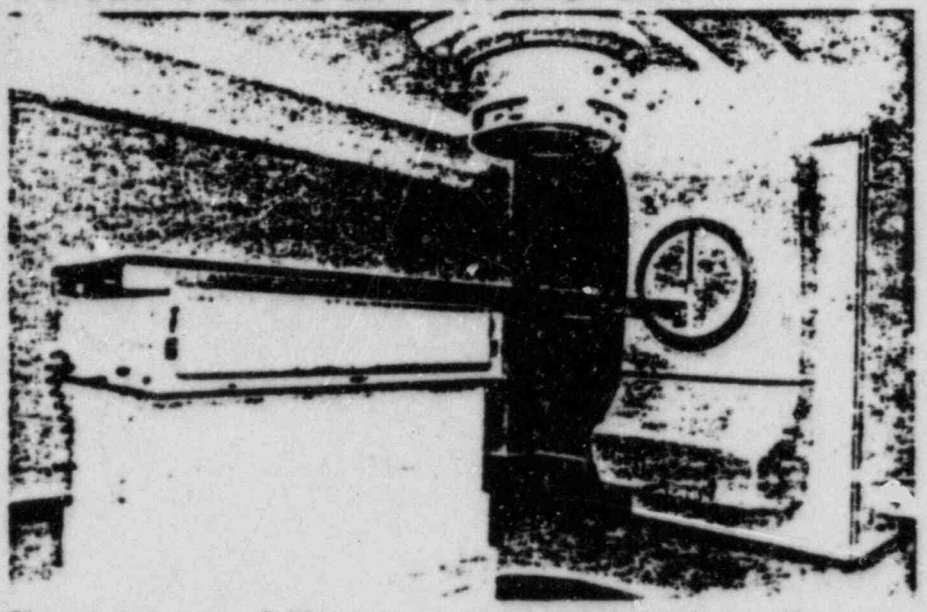
The Pathologist should have a record of autopsies and attendance. These records should correspond to the records in the Radiology Department and the Residents' logs.

The charts and films to be reviewed should be readily available for the inspectors, cross-file index and teaching aids convenient. Anticipate that the inspector will see the library in the Radiology Department as well as the general hospital library for the staff.

Journals for radiology and other departments of the hospital should be available and records of the activities of a Journal Club and participation by the trainees should be documented.

(Continued on Page 4)

Metropolitan Hospital Adds A 4 MV Linear Accelerator



Pictured above is the 4 MV Linear accelerator, recently acquired by Metropolitan Hospital's Radiology Department.

Metropolitan Hospital in Philadelphia is expanding its oncology and radiation therapy services with the installation of a 4 MV Linear Accelerator and with the addition of a radiation oncologist to the staff.

The Clinac 4 Linear Accelerator, manufactured by Varian, will permit radiation management of a wide variety of oncologic problems with a high energy, well-collimated beam providing the advantages of standard megavoltage external beam therapy in terms of patient comfort, skin sparing effect and treatment volume control. The Clinac 4 has the following characteristics. 350 rads/minute output; 3mm focal spot with minimum penumbra, field sized continuously adjustable from 0 x 0 to 32 x 32cm and 360 degree isocenter rotation.

The availability of megavoltage radiation therapy and the presence of a radiation oncologist should provide additional base for expansion of oncologic treatment services at Metropolitan Hospital. This installation is one phase of a long range program which will ultimately result in an in-hospital geographically localized clinical oncology unit, designed for optimum bedside care of the patient with malignant disease and for critical control of patients on drug protocols.

(Continued on Page 4)

VIEWBOX

Publication of the American Osteopathic College of Radiology

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How To Prepare For An Inspection

(Continued from Page 3)

Prepare the equipment for inspection and store extraneous material in the diagnostic and therapy rooms. The film storage should be ready for the inspectors. A flow chart of the work through the department will be evaluated. There should be a time and place for the resident to study. The type, amount and kind of supervision of the resident will be considered. The work load and participation of the resident in the various activities in the department will be scrutinized. More and more emphasis is being put on the variety and volume of special procedures in the department.

If an adequate volume of these are not done in the hospital, documentation of the training in and out of the hospital in these sub-specialties should be available.

If Nuclear Medicine is not a part of the Radiology Department, evidence of the correlation between these departments should be available along with the teaching program for the residents in nuclear medicine.

The residents should be able to document their activities and reflect their understanding of the teaching program, reaction to assignments, work load, hours, time of training outside the department, and hospital policies of attendance of residents at meetings, in and out of hospital professional activities allowed, permitted or expected of the resident, and professional functions outside the department, and their progress to date. Attendance in the resident's log should correspond to attendance records of staff, department, committee meetings and autopsies.

Evidence of their work on the annual thesis, participation in the Candidate-Resident Paper Contest sponsored by the American Osteopathic College of Radiology and their Candidate Membership in the American Osteopathic College of Radiology, Membership in the American Osteopathic Association and their state society should be ready for presentation to the inspector. Any special preparation for the examination by the American Osteopathic Board of Radiology or American Osteopathic Board of Nuclear Medicine should be a part of their report to the inspector.

Preparing for the inspection as above outlined will provide the inspector the best opportunity to make a complete evaluation of the effectiveness of your program.

Open Letter To Malpractice Insurance Carriers Is Sent

Copies of the following letter have been sent to the major malpractice insurance carriers in Pennsylvania.

"At a hearing held by the Insurance Department of Pennsylvania, June 17 and 18, 1974 in Philadelphia, the Pennsylvania Osteopathic Radiology Society petitioned the State Insurance Department to correct the following discriminatory practices against D.O. radiologists practicing in the state of Pennsylvania.

D.O. Radiologists pay significantly higher malpractice premium insurance rates than M.D. radiologists in comparable geographic areas, where the scope of radiology is the same for both groups.

D.O. radiologists who practice general hospital radiology pay significantly higher malpractice premiums for the same coverage compared to M.D. radiologists who practice subspecialty radiology such as, neuroradiology, which carries a higher potential claim risk.

There are very few insurance companies who will underwrite malpractice insurance for D.O. radiologists, and the reasons for the limited choice of companies has never been adequately explained.

In order to lower costs of malpractice premiums, D.O. radiologists have had to join county medical societies to be able to qualify for malpractice insurance coverage. Such membership neither adds nor detracts from the radiologists exposure or potential claim risk.

Some insurance companies have written malpractice coverage for D.O. radiologists only with the understanding that the company would underwrite the applicant's entire insurance needs, i.e., home, auto, life, etc. This type of packaging represents unfair coercion.

We are not aware that insurance companies base malpractice premium rates upon actual claim experience in Pennsylvania.

Although a considerable spread in premium is now present between D.O. and M.D. radiologists practicing under comparable circumstances, there is very little spread in the relative premiums between D.O. and M.D. plastic surgeons and D.O. and M.D. orthopedic surgeons, where the claim risk is higher.

These unfair practices have been engaged in for many years by insurance malpractice carriers in Pennsylvania. An artificially narrow market has been created with high premiums to osteopathic radiologists.

The situation is particularly unfair in view of the fact that osteopathic radiologists are required and do practice their specialty according to the same standards as their M.D. radiologist colleagues.

We will be pleased to print any replies received to this letter in the future issues of Viewbox.

Metropolitan

(Continued from Page 3)

The expanded radiation oncology service will be a cooperative facility of the Hahnemann Treatment Planning Centre-Regional Radiation Therapy Network, and will have available to it the multiple facilities of the centre, such as computer treatment planning and dosimetry, mould room capability, and facilities for recall and analysis of clinical records.

Paul Wallner, D.O. has joined the Metropolitan Hospital staff as radiation oncologist. Dr. Wallner was previously a resident in Radiology at Metropolitan Hospital, a fellow in Radiation Therapy at Hahnemann Medical College Hospital, and chief of the Radiation Therapy service at Madigan General Hospital. Dr. Wallner is also a member of the Department of Radiation Therapy at Hahnemann, and thus can effectively utilize the Treatment Planning Centre facilities for Metropolitan Hospital patients.

It is hoped that at some time in the near future a radiation oncology residency training program will be offered at Metropolitan Hospital, either as a straight radiation oncology program or as a full-time service in a General Radiology program.

Approved AOCR Board of Directors 10/5/79
Approved AOCR 10/9/79

REVISED MINIMAL STANDARDS FOR RESIDENCY TRAINING IN RADIOLOGY

Foreword

The purpose of this document is to:

1. Define specialty training in Radiology.
2. Establish minimal standards and requirements for specialty training in Radiology.
3. Offer suggestions for the implementation of these standards, and to encourage the highest standards of education and practice in the specialty of Radiology.

Time Requirements

RADIOLOGY RESIDENCY PROGRAMS ARE OF 36 MONTHS' DURATION. IN ORDER FOR A PROGRAM TO CARRY THIS DESIGNATION, IT MUST OFFER THE RESIDENT A MINIMUM OF 22 MONTHS IN DIAGNOSTIC RADIOLOGY, 3 MONTHS IN RADIATION ONCOLOGY, 3 MONTHS IN NUCLEAR MEDICINE, 2 MONTHS IN PEDIATRIC RADIOLOGY, 1 MONTH IN DIAGNOSTIC ULTRASOUND, AND 1 MONTH IN COMPUTERIZED AXIAL TOMOGRAPHY. THE REMAINING 4 MONTHS MAY BE SPENT IN RADIOLOGY OR IN SUBSPECIALTY AREAS OF RADIOLOGY.

Approval

Training programs in radiology come within the purview of the Committee on Postdoctoral Training (COPT) of the American Osteopathic Association (AOA), and they must also be approved by the Board of Trustees of the AOA.

The American Osteopathic College of Radiology (AOCR) through its Committee on Evaluation and Educational Standards, works closely with the COPT to maintain high standards for training programs in Radiology. The AOCR also has direct representation on the COPT.

College Role

The AOCR has as its primary goal quality education in the Radiology Residency Program. The Board of Directors of the AOCR strongly feel their responsibility regarding evaluation and educational standards. It is their consensus that training programs as recommended by the College and approved by the AOA offer a diversification of training and adequate preparation for Certification in Radiology and the practice of this specialty.

ATTACHMENT NO. 4

I. Qualifications of PROGRAM DIRECTOR

A. Professional:

1. The Chairman of a Department of Radiology may designate a responsible PROGRAM DIRECTOR. However, this designation of authority does not relieve the Department Chairman from the responsibility of assuring that the residency program meets or exceeds, the recommended "minimal standards."

2. The designated PROGRAM DIRECTOR shall be certified in Radiology

3. The designated PROGRAM DIRECTOR shall be a full-time specialist in Radiology, capable of conducting a broad program in radiologic science, including the clinical aspects of Radiology.

4. He shall have at least five years of post residency experience in hospital Radiology.

5. He shall be a member of the American Osteopathic College of Radiology.

6. He shall meet and continue to meet the Continuing Medical Education (CME) requirements of the American Osteopathic College of Radiology and the American Osteopathic Association.

B. Responsibilities:

1. The PROGRAM DIRECTOR shall be responsible to provide a complete training program in Radiology. This is not meant to imply that all training must be within the parent institution. Outside exposure of residents is encouraged, not discouraged. Acceptable procedures for satisfying deficiencies in a training program may include:
   a. An exchange program
   b. A visitation program outside the parent hospital to strengthen training in special procedures, nuclear medicine, ultrasound, and CT scanning.
   c. College, university or formal course in radiophysics, radiobiology, and radiation protection.
   d. Other recognized courses or seminars.
2. The PROGRAM DIRECTOR SHALL REGISTER ALL RESIDENTS with the Secretary of the American Osteopathic Board of Radiology (AOBR) and the Secretary of the American Osteopathic College of Radiology (AOCR).
3. The PROGRAM DIRECTOR will notify the above-named agencies in the event of a change of status of the residents or training program.
4. The PROGRAM DIRECTOR shall inform the Secretaries of the

AOBR and the AOCR of a RESIDENT'S successful completion of his program.

5. The PROGRAM DIRECTOR will file annual reports with the Secretary of the Committee on Post-Doctoral Training (COPT) of the American Osteopathic Association and Secretary of AOCR.

6. The PROGRAM DIRECTOR will assure that the RESIDENT'S three required papers are of an acceptable nature.

7. The PROGRAM DIRECTOR shall be prepared to document the post-doctoral training of all radiologists within the Department since the last inspection.

8. The PROGRAM DIRECTOR will keep a copy of all required reports.

9. The PROGRAM DIRECTOR will assure that the resident's log and other records are maintained and up to date.

II. Department Requirements

1. The Radiology Department shall have an adequate records system for all procedures performed and a satisfactory pathologic cross file index using standard disease nomenclature such as that established by the American College of Radiology.

2. The Radiology Library shall contain a sufficient number of current and established texts covering the fields of diagnostic radiology, oncology, ultrasound, CT scanning and nuclear medicine as well as current texts in general medicine and surgery in their various branches. The Library will contain a reasonable number of appropriate and current journals related to the radiological sciences. The radiology library should preferably be housed within the department rather than the general hospital library. AN ADEQUATE UP-TO-DATE TEACHING FILE IN THE FIELDS OF DIAGNOSTIC RADIOLOGY, RADIATION ONCOLOGY, NUCLEAR MEDICINE, ULTRASOUND AND CT SCANNING WILL BE MAINTAINED WITHIN THE RADIOLOGY DEPARTMENT.

3. The Department should be physically arranged to provide space and atmosphere conducive to resident study and conferences.

4. There shall be a minimum number of full-time radiologists as follows: 2 radiologists for 1 resident, 3 radiologists for 2 residents, and thereafter an adequate number of full-time radiologists to insure a successfully supervised and structured program.

ATTACHMENT NO. 4

5. The department should have available facilities for clinical photography. This should enhance the teaching program and develop the RESIDENT'S interest in this activity.

6. The Radiology department work census or audit must have sufficient scope to expose the RESIDENT to a representative range of procedures and pathology.

   a. THE MINIMUM NUMBER OF DIAGNOSTIC PROCEDURES TO QUALIFY FOR A TRAINING PROGRAM SHALL BE 30,000 PER YEAR. A PROCEDURE IS DEFINED AS AN EXAMINATION OR STUDY OF A GIVEN CASE (X-RAY, NUCLEAR MEDICINE, OR DIAGNOSTIC ULTRASOUND). A CASE, HOWEVER, MAY INCLUDE SEVERAL PROCEDURES OR EXAMINATIONS: For instance, CHEST, STOMACH AND COLON FOR A TOTAL OF THREE EXAMINATIONS OR PROCEDURES.

   b. The RESIDENT shall be exposed to an adequate cross section of special procedures to gain a working knowledge of such procedures on which to build future experience. Program deficiencies in this respect shall be satisfied by documented visitation or affiliation outside the parent institution.

III. Department Equipment

A. DIAGNOSTIC

1. DIAGNOSTIC EQUIPMENT SHALL BE OF MODERN DESIGN AND SHALL MEET THE REQUIREMENTS AND STANDARDS OF FEDERAL, STATE OR LOCAL REGULATIONS.

2. Equipment will be consistent with the workload of the department:

   a. Fluoroscopic equipment will include image intensification, preferably with television display.

   b. Generators will carry ratings consistent with the workload placed upon them.

   c. At least one room will be equipped with tomographic apparatus.

   d. At least single plane, rapid cassette changers will be available for arteriographic studies if performed within the institution.

   e. Mobile units will be of sufficient rating to provide for adequate diagnostic studies.

3. The following equipment and/or facilities are desirable but not mandatory:

   a. Xeroradiography
   b. Computerized axial tomography
   c. Diagnostic Ultrasound
   d. Microfilming
   e. Cine or equivalent
   f. Video tape equipment

B. NUCLEAR MEDICINE

1. It is desirable but not mandatory, that nuclear medicine come under the jurisdiction of the Department of Radiology.

2. IT IS RECOMMENDED THAT THE MINIMUM EQUIPMENT IN A NUCLEAR MEDICINE SECTION INCLUDE:

   A. CAMERA OF MODERN DESIGN
   B. IMAGING DEVICE WITH WHOLE BODY CAPABILITY, EITHER CAMERA OR RECTILINEAR SCANNER
   C. PHYSIOLOGIC TIMING - NUCLEAR CARDIOLOGY
   D. COMPUTER OR DATA PROCESSOR
   E. DOSE CALIBRATOR AND RELATED QUALITY CONTROL EQUIPMENT NECESSARY IN THE PREPARATION OF RADIOPHARMACEUTICALS
   F. COMPLETE IN VITRO LABORATORY EQUIPMENT ABLE TO HANDLE ROUTINE IN VITRO STUDIES SUCH AS BLOOD VOLUME, RED CELL SURVIVAL, FERROKINETICS, AND RADIOIMMUNOASSAY
   G. MONITORING EQUIPMENT CONSISTENT WITH NRC RADIATION SAFETY REQUIREMENTS
   H. EQUIPMENT APPROPRIATE TO PREPARING AND DELIVERING RADIONUCLIDES FOR ISOTOPE THERAPY
   I. PHANTOMS AND PROCEDURES ASSURING QUALITY CONTROL

3. Equipment capable of performing dynamic flow studies.

4. Technicians operating nuclear medicine facilities should be appropriately trained.

5. If nuclear medicine is not administered under the Department of Radiology, training elsewhere in the parent institution must be documented as if taken outside the parent institution.

6. In the event that nuclear medicine is not available within the parent institution, an adequately documented outside program must be developed. Documentation of outside training in nuclear medicine must conform to the format approved by the American Osteopathic College of Radiology.

ATTACHMENT NO. 4

C. ULTRASOUND

1. THE ULTRASOUND DEPARTMENT SHOULD COME UNDER THE JURISDICTION OF THE DEPARTMENT OF RADIOLOGY.
2. EQUIPMENT (MAY INCLUDE DOPPLER AND ECHOCARDIOGRAPHY) SHOULD MEET THE STANDARDS OF MODERN TECHNOLOGY.
3. ULTRASOUND TECHNICIANS SHOULD BE APPROPRIATELY TRAINED.
4. THERE SHALL BE PHANTOMS AND PROCEDURES ASSURING QUALITY CONTROL.

D. COMPUTERIZED AXIAL TOMOGRAPHY

1. THE COMPUTERIZED AXIAL TOMOGRAPHY DEPARTMENT SHOULD COME UNDER THE JURISDICTION OF THE DEPARTMENT OF RADIOLOGY.
2. THE EQUIPMENT SHOULD MEET THE STANDARDS OF MODERN TECHNOLOGY.
3. TECHNICIANS OPERATING EQUIPMENT SHOULD BE APPROPRIATELY TRAINED.
4. THERE SHALL BE PROCEDURES, PHANTOMS, AND PHYSICIST SUPPORT TO ASSURE QUALITY CONTROL.

E. RADIATION ONCOLOGY

1. THE RADIATION ONCOLOGY DEPARTMENT SHOULD COME UNDER THE JURISDICTION OF THE DEPARTMENT OF RADIOLOGY.
2. THE RADIATION THERAPY EQUIPMENT SHOULD MEET THE STANDARDS OF MODERN TECHNOLOGY.
3. RECOMMENDED EQUIPMENT SHALL INCLUDE SUPERFICIAL ORTHOVOLTAGE AND SUPERVOLTAGE THERAPY UNITS.
4. EQUIPMENT SHOULD BE CALIBRATED AT LEAST ANNUALLY OR MORE OFTEN AS LOCAL REGULATORY AGENCIES REQUIRE.
5. IT IS RECOMMENDED THAT ADEQUATE SUPPORT PERSONNEL, I.E., RADIATION PHYSICIST, DOSIMETRIST BE AVAILABLE.
6. IT IS RECOMMENDED THAT THE DEPARTMENT SHOULD HAVE SUFFICIENT RADIUM OR ITS EQUIVALENT ALONG WITH A VARIETY OF APPLICATORS FOR SAFE AND APPROPRIATE SURFACE AND INTRACAVITARY APPLICATIONS.

IV. Safety Program

1. A radiological safety officer will be designated.

2. Adequate protection for all personnel and patients exposed to radiation shall be maintained.

3. Standards for protection of personnel and patients shall equal those established by the Public Health Service and the Bureau of Standards. Where state law requires, standards will be in compliance.

4. Fluoroscopy records will be maintained in accordance with AOA requirements.

V. EDUCATIONAL PROGRAM

A. Minimum Basic Science Requisites:

1. It is assumed that the RESIDENT has a background of physics, obtained through pre-osteopathic professional education.

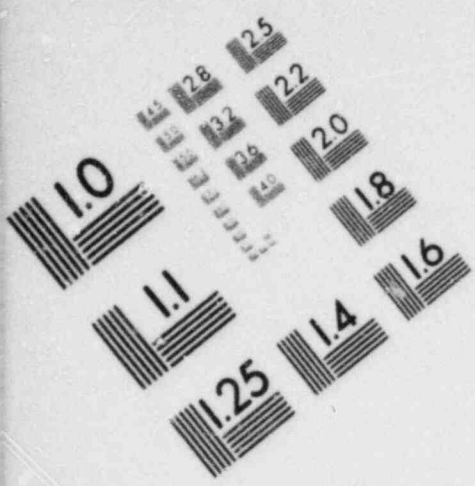
2. Ideally, a formal training program of 80 hours of instruction in basic electricity and x-ray, and nuclear physics should be given. When this 80-hour program cannot be given, a minimum of 40 hours of intensive training shall be given by a qualified physicist. This should be supplemented by regular weekly instruction in the department to establish a meaningful relationship between the training and the problems encountered in clinical radiology.

3. A minimum of 24 hours of formal instruction in radiation biology should be given. This includes cellular and subcellular effects, tissue kinetics and responses, factors modifying effects, total body effects and histopathological responses.

4. The RESIDENT should receive oncology training through collaboration of the radiation oncology service with the departments of pathology, medicine, and surgery. He should correlate his oncology experience through clinicopathologic conferences and autopsies. This is best done by integrated conference programming.

5. THE MINIMUM TIME REQUIREMENT FOR SPECIALTY TRAINING IN NUCLEAR MEDICINE SHALL BE THREE MONTHS. THIS SHOULD OFFER APPROPRIATE TRAINING IN PHYSICS, INSTRUMENTATION, RADIOPHARMACOLOGY, RADIATION PROTECTION, CLINICAL EVALUATION OF PATIENTS AND PARTICIPATION IN PERFORMANCE AND INTERPRETATION OF NUCLEAR STUDIES. THESE THREE MONTHS NEED NOT BE CONTINUOUS. IT IS RECOMMENDED THAT THE PROGRAM QUALIFY THE RESIDENT FOR LICENSURE BY THE NUCLEAR REGULATORY COMMISSION. THE RESIDENT SHOULD BE TRAINED IN BASIC RADIOPHARMACY PRINCIPLES IN DOSE PREPARATION, HANDLING, ADMINISTRATION AND DISPOSAL. THE RESIDENT SHOULD BE TRAINED TO OPERATE THE EQUIPMENT IN ORDER TO PERFORM ROUTINE RADIONUCLIDE ORGAN IMAGING.

6. PEDIATRIC RADIOLOGY SOULD BE INTEGRATED OVER THE THREE YEAR PROGRAM. HOWEVER, WHERE THE TRAINING HOSPITAL PEDIATRIC CLINICAL FACILITIES ARE LACKING IN SUFFICIENT PEDIATRIC CASE MATERIAL AND PROCEDURES, OUTSIDE ROTATION FOR TWO MONTHS IN A PEDIATRIC RADIOLOGY DEPARTMENT IS RECOMMENDED.



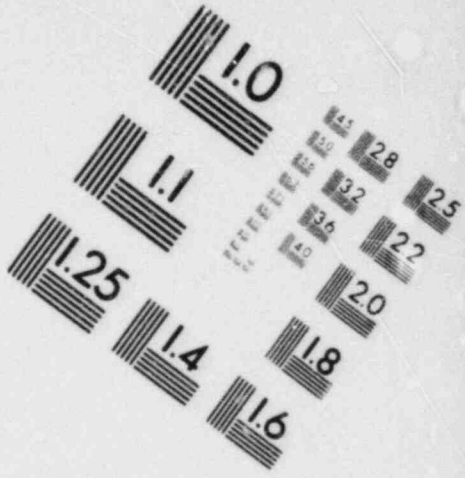


IMAGE EVALUATION
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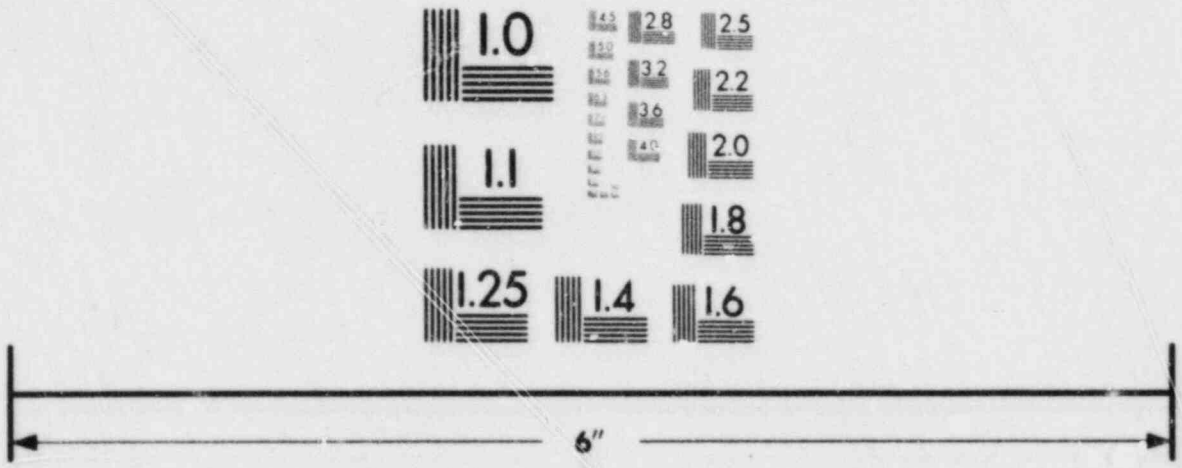
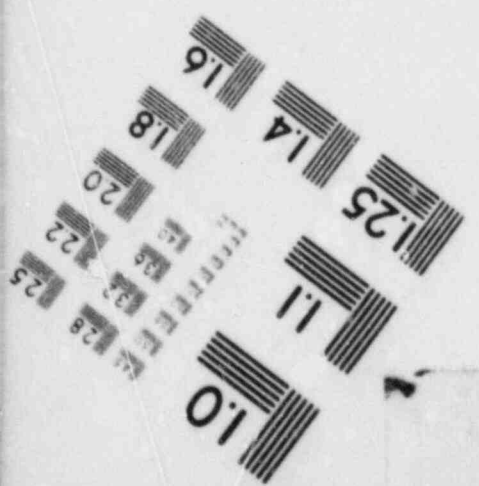
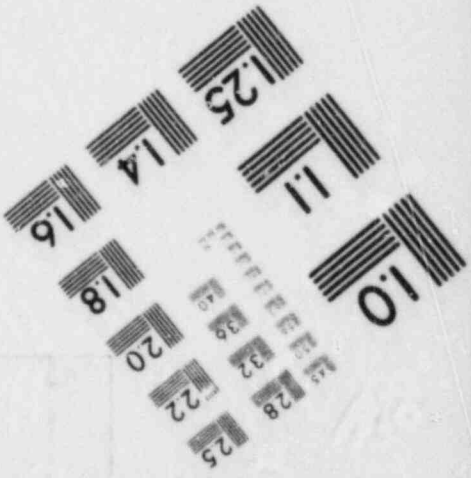
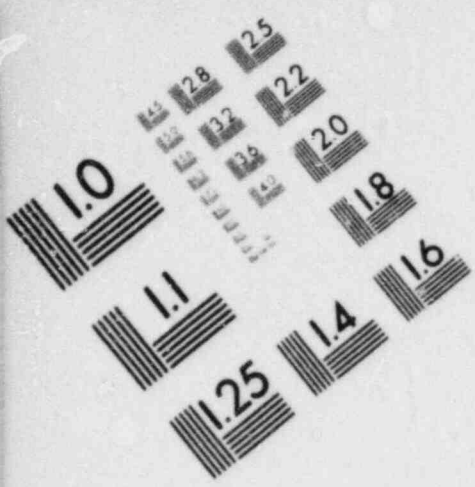
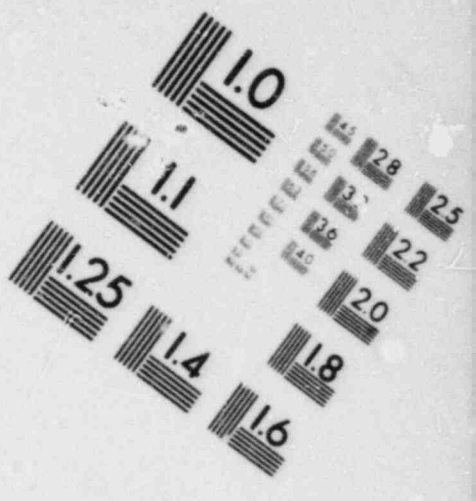


MICROCOPY RESOLUTION TEST CHART









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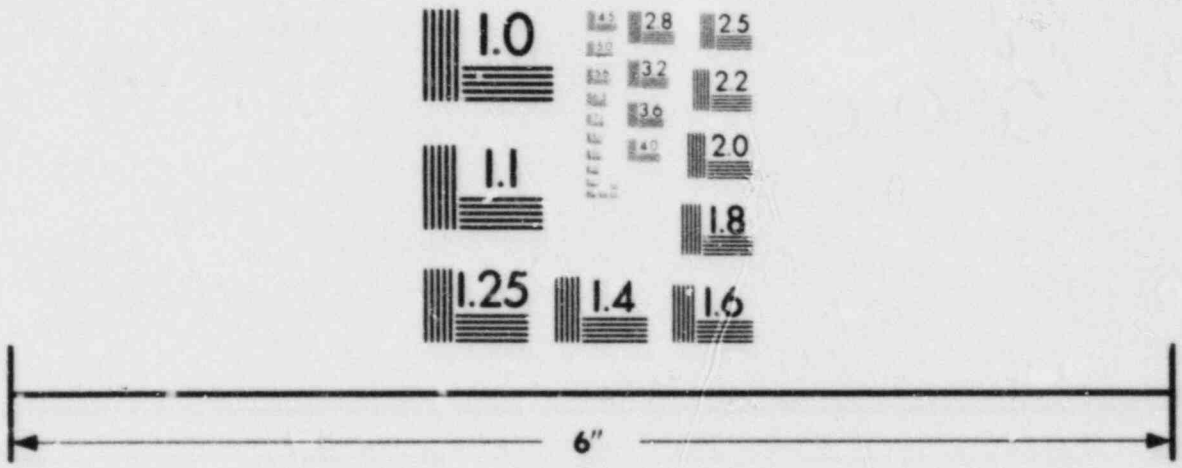
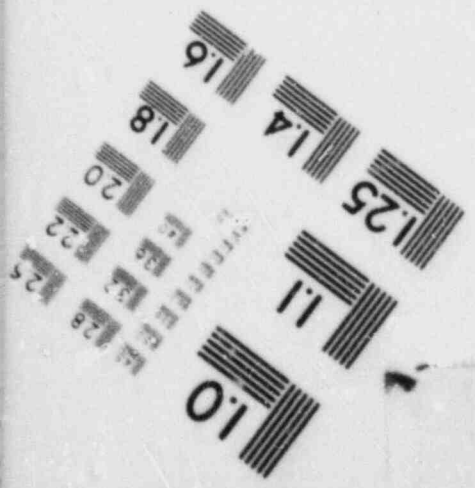
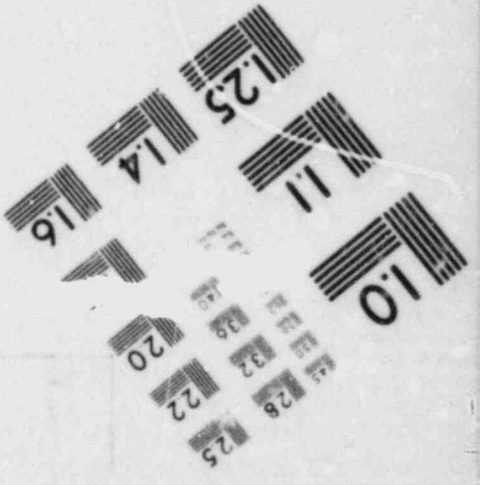


MICROCOPY RESOLUTION TEST CHART





7. TRAINING IN DIAGNOSTIC ULTRASOUND IDEALLY SHOULD BE INTEGRATED OVER THE THREE YEAR PERIOD OF THE RESIDENCY. DURING THIS TIME, THE RESIDENT SHOULD OBSERVE AND ASSIST THE PERFORMANCE AND INTERPRETATION OF THE VARIOUS PROCEDURES AND SUPPLEMENT THIS WORK WITH A CORRELATED, DIRECTED READING PROGRAM. IF ULTRASONOGRAPHY IS NOT AVAILABLE IN THE PARENT INSTITUTION, SUITABLE COURSES AND EXPOSURE SHOULD BE MADE AVAILABLE TO GIVE THE RESIDENT AN EQUIVALENT OF ONE MONTH'S TRAINING. THE RESIDENT SHOULD BE TRAINED TO PERFORM AND INTERPRET ROUTINE PELVIC AND ABDOMINAL ULTRASOUND STUDIES.

8. TRAINING IN COMPUTERIZED AXIAL TOMOGRAPHY SHOULD BE INTEGRATED OVER THE THREE YEAR PERIOD OF THE RESIDENCY. IF CT FACILITIES ARE NOT AVAILABLE IN THE TRAINING HOSPITAL, SUITABLE COURSES AND TRAINING SHOULD BE MADE AVAILABLE TO GIVE THE RESIDENT AN EQUIVALENT OF ONE MONTH FORMAL TRAINING IN COMPUTERIZED AXIAL TOMOGRAPHY.

9. THE RESIDENT SHALL SPEND NO LESS THAN THREE MONTHS IN RADIATION ONCOLOGY. IF RADIATION ONCOLOGY TRAINING IS NOT AVAILABLE IN THE PARENT HOSPITAL, A DOCUMENTED THREE-MONTH OUTSIDE ROTATION IS RECOMMENDED. IT IS NOT THE PURPOSE OF THIS THREE MONTH TRAINING IN RADIATION ONCOLOGY TO ATTEMPT TO TRAIN A RADIATION THERAPIST. SUCH TASK WOULD REQUIRE AN AOCR APPROVED RESIDENCY PROGRAM LIMITED TO RADIATION ONCOLOGY. THE RESIDENT SHALL HAVE ADEQUATE EXPOSURE TO ALL PHASES OF RADIATION ONCOLOGY INCLUDING SUPERFICIAL ORTHOVOLTAGE, SUPERVOLTAGE AND INTRACAVITARY EXPERIENCE. THIS THREE MONTH PERIOD SHOULD DEVELOP BASIC UNDERSTANDING OF THE DISCIPLINES OF RADIATION ONCOLOGY AND THEIR APPLICATION IN THE EARLY DIAGNOSIS, ADEQUATE TREATMENT AND FOLLOW-UP OF THE CANCER PATIENT. THIS EXPERIENCE SHOULD ENABLE THE RESIDENT TO DETERMINE DEGREE OF INTEREST IN FUTURE SPECIALTY PRACTICE IN RADIATION ONCOLOGY.

B. General Requisites:

1. Formal training in radiophysics, radiobiology, basic techniques in handling of radioisotopes, radiation protection shall be provided to qualify the RESIDENT for successful application for NRC license for the diagnostic use of byproduct materials.

2. If such education or training is not available in a given department, a service affiliation shall be required to enable the program to comply satisfactorily with these requirements.

3. A formal, progressive and comprehensive program must be laid down and followed during the training period. The program may be developed by the PROGRAM DIRECTOR or it

may be modeled after another program approved by the AOCR. If a PROGRAM DIRECTOR elects to develop his own program, he shall first submit it for approval to the Committee on Evaluation and Educational Standards of the AOCR and the Committee on Postdoctoral Training of the AOA.

C. Other Requisites:

1. The training program in radiologic science shall require an integration of training with other departments such as surgery, pathology, medicine, and pediatrics.

2. The RESIDENT shall follow patients to surgery, correlating radiologic findings. He shall participate in surgical and other conferences whenever possible.

3. The RESIDENT shall follow cases to pathology to develop an appreciation of gross pathology of surgical specimens, and he shall review gross and microscopic findings of tissue in cases of special interest to the department of radiology. He shall attend autopsies, especially those of interest to the Radiology Department, and he shall participate in clinicopathological conferences.

4. The RESIDENT shall, through conference techniques or other suitable means, be provided training in correlating radiologic findings with those of medicine and surgery.

5. The RESIDENT shall keep a log during his training program, which shall be reported monthly to the PROGRAM DIRECTOR with copies to the Director of Medical Education of the hospital. The format of the log may be patterned after that recommended by the Committee on Evaluation and Educational Standards of the AOCR or developed by the PROGRAM DIRECTOR. The resident log shall document the radiation oncology exposure including case volume and breakdown of disease category with special listing of radium cases, formal courses, tumor board and conference attendance, and read-in assignments.

   a. Documentation of outside training must conform to the format approved by the AOCR.

6. The RESIDENT shall be required to prepare one paper annually and send a copy to the Secretary of the College.

7. IT IS RECOMMENDED THAT THE RESIDENT APPLY FOR CANDIDATE MEMBERSHIP IN THE AOCR DURING THE FIRST YEAR OF RESIDENCY.

8. THE RESIDENT, AT THE INITIATION OF THE PROGRAM, SHALL RECEIVE A COPY OF THE PROGRAM SYLLABUS AND THE DOCUMENT OF MINIMAL STANDARDS FOR TRAINING IN THE RADIOLOGICAL SCIENCES.

Candidate Selection:

1. Candidates shall be graduates of Colleges of Osteopathic Medicine approved by the American Osteopathic Association.

2. Candidates shall be members in good standing of local, state and national osteopathic societies.

3. Candidates shall have completed at least one year of internship approved by the AOA.

4. Candidates shall exhibit the following qualities that are known to be requisite to the successful practice of the specialty of Radiology:

   Candidates shall be well-motivated and well-rounded physicians, have a desire to read and keep abreast of the times in a rapidly changing specialty, an interest in research, and possess a broad philosophy of diagnosis and treatment of disease. This will preclude a narrow concept of Radiology. The candidate shall have an adequate understanding of the osteopathic concept.

5. Candidates shall be thoroughly grounded in the Code of Ethics of the AOA, which shall be a guide for them in their practice of Radiology.

VII. Educational Objectives:

The training program in Radiology is a full-time, three-year residency. The educational objectives of this training program are as follows:

1. Basic and advanced training in radiology on a post-graduate basis.

2. Certification by the American Osteopathic Board of Radiology.

MINIMAL STANDARDS FOR RESIDENCY TRAINING IN DIAGNOSTIC RADIOLOGY

Foreword

The purpose of this document is to:

1. Define specialty training in Diagnostic Radiology.
2. Establish minimal standards and requirements for specialty training in Diagnostic Radiology.
3. Offer suggestions for the implementation of these standards and to encourage the highest standards of education and practice in the specialty of Diagnostic Radiology.

Time Requirements

DIAGNOSTIC RADIOLOGY RESIDENCY PROGRAMS ARE OF 36 MONTHS' DURATION. IN ORDER FOR A PROGRAM TO CARRY THIS DESIGNATION, IT MUST OFFER THE RESIDENT A MINIMUM OF 22 MONTHS IN DIAGNOSTIC RADIOLOGY, 3 MONTHS IN NUCLEAR MEDICINE, 1 MONTH IN DIAGNOSTIC ULTRASOUND, 1 MONTH IN COMPUTERIZED AXIAL TOMOGRAPHY, AND 2 MONTHS IN PEDIATRIC RADIOLOGY. THE REMAINING 7 MONTHS MAY BE SPENT IN DIAGNOSTIC RADIOLOGY OR IN SUBSPECIALTY AREAS OF RADIOLOGY.

Approval

Training programs in diagnostic radiology come within the purview of the Committee on Postdoctoral Training (COPT) of the American Osteopathic Association (AOA), and they must also be approved by the Board of Trustees of the AOA.

The American Osteopathic College of Radiology (AOCR) through its Committee on Evaluation and Educational Standards, works closely with the COPT to maintain high standards for training programs in Diagnostic Radiology. The AOCR also has direct representation on the COPT.

College Role

The AOCR has as its primary goal quality education in the Diagnostic Radiology Residency Program. The Board of Directors of the AOCR strongly feel their responsibility regarding evaluation and educational standards. It is their consensus that training programs as recommended by the College and approved by the AOA offer a diversification of training and adequate preparation for Certification in Diagnostic Radiology and the practice of this specialty.

ATTACHMENT NO. 4

I. Qualifications of PROGRAM DIRECTOR

A. Professional:

1. The Chairman of a Department of Radiology may designate a responsible PROGRAM DIRECTOR, However, this designation of authority does not relieve the Department Chairman from the responsibility of assuring that the residency program meets or exceeds, the recommended "minimal standards."

2. The designated PROGRAM DIRECTOR shall be certified in Diagnostic Radiology or Radiology.

3. The designated PROGRAM DIRECTOR shall be a full-time specialist in Diagnostic radiology, capable of conducting a broad program in radiologic science, including the clinical aspects of Diagnostic Radiology.

4. He should have at least five years of post residency experience in hospital Diagnostic Radiology.

5. He shall be a member of the American Osteopathic College of Radiology.

6. He shall meet and continue to meet, the Continuing Medical Education (CME) requirements of the American Osteopathic College of Radiology and the American Osteopathic Association.

B. Responsibilities:

1. The PROGRAM DIRECTOR shall be responsible to provide a complete training program in Diagnostic Radiology. This is not meant to imply that all training must be within the parent institution. Outside exposure of residents is encouraged, not discouraged. Acceptable procedures for satisfying deficiencies in a training program may include:
   a. An exchange program
   b. A visitation program outside the parent hospital to stengthen training in special procedures, nuclear medicine, ultrasound, and CT scanning.
   c. College, university or formal course in radiophysics, radiobiology, and radiation protection.
   d. Other recognized courses or seminars.

2. The PROGRAM DIRECTOR SHALL REGISTER ALL RESIDENTS with the Secretary of the American Osteopathic Board of Radiology (AOBR) and the Secretary of the American Osteopathic College of Radiology (AOCR).
3. The PROGRAM DIRECTOR will notify the above-named agencies in the event of a change of status of the residents or training program.
4. The PROGRAM DIRECTOR shall inform the Secretaries of the

AOBR and the AOCR of a RESIDENT'S successful completion of his program.

5. The PROGRAM DIRECTOR will file annual reports with the Secretary of the Committee on Post-Doctoral Training (COPT) of the American Osteopathic Association and Secretary of AOCR.

6. The PROGRAM DIRECTOR will assure that the RESIDENT'S three required papers are of an acceptable nature.

7. The PROGRAM DIRECTOR shall be prepared to document the post-doctoral training of all radiologists within the Department since the last inspection.

8. The PROGRAM DIRECTOR will keep a copy of all required reports.

9. The PROGRAM DIRECTOR will assure that the resident's log and other records are maintained and up to date.

II. Department Requirements

1. The Radiology Department shall have an adequate records system for all procedures performed and a satisfactory pathologic cross file index using standard disease nomenclature such as that established by the American College of Radiology.

2. The Radiology Library shall contain a sufficient number of current and established texts covering the fields of diagnostic radiology, oncology, ultrasound, CT scanning and nuclear medicine as well as current texts in general medicine and surgery in their various branches. The Library will contain a reasonable number of appropriate and current journals related to the radiological sciences. The radiology library should preferably be housed within the department rather than the general hospital library. AN ADEQUATE UP-TO-DATE TEACHING FILE IN THE FIELDS OF DIAGNOSTIC RADIOLOGY, NUCLEAR MEDICINE, ULTRASOUND AND CT SCANNING WILL BE MAINTAINED WITHIN THE RADIOLOGY DEPARTMENT.

3. The Department should be physically arranged to provide space and atmosphere conducive to resident study and conferences.

4. There shall be a minimum number of full-time radiologists as follows: 2 radiologists for 1 resident, 3 radiologists for 2 residents, and thereafter an adequate number of full-time radiologists to insure a successfully supervised and structured program.

5. The department should have available facilities for clinical photography. This should enhance the teaching program and develop the RESIDENT'S interest in this activity.

6. The Radiology department work census or audit must have sufficient scope to expose the RESIDENT to a representative range of procedures and pathology.

   a. THE MINIMUM NUMBER OF DIAGNOSTIC PROCEDURES TO QUALIFY FOR A TRAINING PROGRAM SHALL BE 30,000 PER YEAR. A PROCEDURE IS DEFINED AS AN EXAMINATION OR STUDY OF A GIVEN CASE (X-RAY, NUCLEAR MEDICINE OR DIAGNOSTIC ULTRASOUND). A CASE, HOWEVER, MAY INCLUDE SEVERAL PROCEDURES OR EXAMINATIONS: FOR INSTANCE, CHEST, STOMACH AND COLON, FOR A TOTAL OF THREE EXAMINATIONS OR PROCEDURES.

   b. The RESIDENT shall be exposed to an adequate cross section of special procedures to gain a working knowledge of such procedures on which to build future experience. Program deficiencies in this respect shall be satisfied by documented visitation or affiliation outside the parent institution.

III. Department Equipment

A. DIAGNOSTIC

1. DIAGNOSTIC EQUIPMENT SHALL BE OF MODERN DESIGN AND SHALL MEET THE REQUIREMENTS AND STANDARDS OF FEDERAL, STATE OR LOCAL REGULATIONS.

2. Equipment will be consistent with the workload of the department:

   a. Fluoroscopic equipment will include image intensification, preferably with television display.

   b. Generators will carry ratings consistent with the workload placed upon them.

   c. At least one room will be equipped with tomographic apparatus.

   d. At least single plane, rapid cassette changers will be available for arteriographic studies if performed within the institution.

   e. Mobile units will be of sufficient rating to provide for adequate diagnostic studies.

ATTACHMENT NO. 4

3. The following equipment and/or facilities are desirable but not mandatory:

   a. Xeroradiography
   b. Computerized axial tomography
   c. Diagnostic Ultrasound
   d. Microfilming
   e. Cine or equivalent
   f. Video tape equipment

B. NUCLEAR MEDICINE

1. It is desirable but not mandatory, that nuclear medicine come under the jurisdiction of the Department of Radiology.

2. IT IS RECOMMENDED THAT THE MINIMUM EQUIPMENT IN A NUCLEAR MEDICINE SECTION INCLUDE:

   A. CAMERA OF MODERN DESIGN
   B. IMAGING DEVICE WITH WHOLE BODY CAPABILITY, EITHER CAMERA OR RECTILINEAR SCANNER
   C. PHYSIOLOGIC TIMING - NUCLEAR CARDIOLOGY
   D. COMPUTER OR DATA PROCESSOR
   E. DOSE CALIBRATOR AND RELATED QUALITY CONTROL EQUIPMENT NECESSARY IN THE PREPARATION OF RADIOPHARMACEUTICALS
   F. COMPLETE IN VITRO LABORATORY EQUIPMENT ADLE TO HANDLE ROUTINE IN VITRO STUDIES SUCH AS BLOOD VOLUME, RED CELL SURVIVAL, FERROKINETICS, AND RADIOIMMUNOASSAY
   G. MONITORING EQUIPMENT CONSISTENT WITH NRC RADIATION SAFETY REQUIREMENTS
   H. EQUIPMENT APPROPRIATE TO PREPARING AND DELIVERING RADIONUCLIDES FOR ISOTOPE THERAPY
   I. PHANTOMS AND PROCEDURES ASSURING QUALITY CONTROL

3. Equipment capable of performing dynamic flow studies.

4. Technicians operating nuclear medicine facilities should be appropriately trained.

5. If nuclear medicine is not administered under the Department of Radiology, training elsewhere in the parent institution must be documented as if taken outside the parent institution.

6. In the event that nuclear medicine is not available within the parent institution, an adequately documented outside program must be developed. Documentation of outside training in nuclear medicine must conform to the format approved by the American Osteopathic College of Radiology.

C. ULTRASOUND

1. THE ULTRASOUND DEPARTMENT SHOULD COME UNDER THE JURISDICTION OF THE DEPARTMENT OF RADIOLOGY.
2. EQUIPMENT (MAY INCLUDE DOPPLER AND ECHOCARDIOGRAPHY) SHOULD MEET THE STANDARDS OF MODERN TECHNOLOGY.
3. ULTRASOUND TECHNICIANS SHOULD BE APPROPRIATELY TRAINED.
4. THERE SHALL BE PHANTOMS AND PROCEDURES ASSURING QUALITY CONTROL.

D. COMPUTERIZED AXIAL TOMOGRAPHY

1. THE COMPUTERIZED AXIAL TOMOGRAPHY DEPARTMENT SHOULD COME UNDER THE JURISDICTION OF THE DEPARTMENT OF RADIOLOGY.
2. THE EQUIPMENT SHOULD MEET THE STANDARDS OF MODERN TECHNOLOGY.
3. TECHNICIANS OPERATING EQUIPMENT SHOULD BE APPROPRIATELY TRAINED.
4. THERE SHALL BE PROCEDURES, PHANTOMS, AND PHYSICIST SUPPORT TO ASSURE QUALITY CONTROL.

IV. Safety Program

1. A radiological safety officer will be designated.

2. Adequate protection for all personnel and patients exposed to radiation shall be maintained.

3. Standards for protection of personnel and patients shall equal those established by the Public Health Service and the Bureau of Standards. Where state law requires, standards will be in compliance.

4. Fluoroscopy records will be maintained in accordance with AOA requirements.

V. Educational Program

A. Minimum Basic Science Requisites:

1. It is assumed that the RESIDENT has a background of physics, obtained through pre-osteopathic professional education.

2. Ideally, a formal training program of 80 hours of instruction in basic electricity and x-ray, and nuclear physics should be given. When this 80-hour program cannot be given, a minimum of 40 hours of intensive training shall be given by a qualified physicist. This should be supplemented by regular weekly instruction in the department to establish a meaningful relationship between the training and the problems encountered in clinical radiology.

3. A minimum of 24 hours of formal instruction in radiation biology should be given. This includes cellular and subcellular effects, tissue kinetics and responses, factors modifying effects, total body effects and histopathological responses.

4. The RESIDENT should receive oncology training through collaboration of the radiation oncology service with the departments of pathology, medicine, and surgery. He should correlate his oncology experience through clinicopathologic conferences and autopsies. This is best done by integrated conference programming.

5. THE MINIMUM TIME REQUIREMENT FOR SPECIALTY TRAINING IN NUCLEAR MEDICINE SHALL BE THREE MONTHS. THIS SHOULD OFFER APPROPRIATE TRAINING IN PHYSICS, INSTRUMENTATION, RADIOPHARMACOLOGY, RADIATION PROTECTION, CLINICAL EVALUATION OF PATIENTS AND PARTICIPATION IN PERFORMANCE AND INTERPRETATION OF NUCLEAR STUDIES. THESE THREE MONTHS NEED NOT BE CONTINUOUS. IT IS RECOMMENDED THAT THE PROGRAM QUALIFY THE RESIDENT FOR LICENSURE BY THE NUCLEAR REGULATORY COMMISSION. THE RESIDENT SHOULD BE TRAINED IN BASIC RADIOPHARMACY PRINCIPLES IN DOSE PREPARATION, HANDLING, ADMINISTRATION AND DISPOSAL. THE RESIDENT SHOULD BE TRAINED TO OPERATE THE EQUIPMENT IN ORDER TO PERFORM ROUTINE RADIONUCLIDE ORGAN IMAGING.

6. PEDIATRIC RADIOLOGY SHOULD BE INTEGRATED OVER THE THREE YEAR PROGRAM. HOWEVER, WHERE THE TRAINING HOSPITAL PEDIATRIC CLINICAL FACILITIES ARE LACKING IN SUFFICIENT PEDIATRIC CASE MATERIAL AND PROCEDURES, OUTSIDE ROTATION FOR TWO MONTHS IN A PEDIATRIC RADIOLOGY DEPARTMENT IS RECOMMENDED.

7. TRAINING IN DIAGNOSTIC ULTRASOUND IDEALLY SHOULD BE INTEGRATED OVER THE THREE YEAR PERIOD OF THE RESIDENCY. DURING THIS TIME, THE RESIDENT SHOULD OBSERVE AND ASSIST THE PERFORMANCE AND INTERPRETATION OF THE VARIOUS PROCEDURES AND SUPPLEMENT THIS WORK WITH A CORRELATED, DIRECTED READING PROGRAM. IF ULTRASONOGRAPHY IS NOT AVAILABLE IN THE PARENT INSTITUTION, SUITABLE COURSES AND EXPOSURE SHOULD BE MADE AVAILABLE TO GIVE THE RESIDENT AN EQUIVALENT OF ONE MONTH'S TRAINING. THE RESIDENT SHOULD BE TRAINED TO PERFORM AND INTERPRET ROUTINE PELVIC AND ABDOMINAL ULTRASOUND STUDIES.

8. TRAINING IN COMPUTERIZED AXIAL TOMOGRAPHY SHOULD BE INTEGRATED OVER THE THREE YEAR PERIOD OF THE RESIDENCY. IF CT FACILITIES ARE NOT AVAILABLE IN THE TRAINING HOSPITAL, SUITABLE COURSES AND TRAINING SHOULD BE MADE AVAILABLE TO GIVE THE RESIDENT AN EQUIVALENT OF ONE MONTH FORMAL TRAINING IN COMPUTERIZED AXIAL TOMOGRAPHY.

B. General Requisites:

1. Formal training in radiophysics, radiobiology, basic techniques in handling of radioisotopes, radiation protection shall be provided to qualify the RESIDENT for successful application for NRC license for the diagnostic use of byproduct materials.

2. If such education or training is not available in a given department, a service affiliation shall be required to enable the program to comply satisfactorily with these requirements.

3. A formal, progressive and comprehensive program must be laid down and followed during the training period. The program may be developed by the PROGRAM DIRECTOR or it may be modeled after another program approved by the AOCR. If a PROGRAM DIRECTOR elects to develop his own program, he shall first submit it for approval to the Committee on Evaluation and Educational Standards of the AOCR and the Committee on Postdoctoral Training of the AOA.

C. Other Requisites:

1. The training program in radiologic science shall require an integration of training with other departments such as surgery, pathology, medicine and pediatrics.

2. The RESIDENT shall follow patients to surgery, correlating radiologic findings. He shall participate in surgical and other conferences whenever possible.

3. The RESIDENT shall follow cases to pathology to develop an appreciation of gross pathology of surgical specimens, and he shall review gross and microscopic findings of tissue in cases of special interest to the department of radiology. He shall attend autopsies, especially those of interest to the Radiology Department, and he shall participate in clinico-pathological conferences.

4. The RESIDENT shall, through conference techniques or other suitable means, be provided training in correlating radiologic findings with those of medicine and surgery.

5. The RESIDENT shall keep a log during his training program which shall be reported monthly to the PROGRAM DIRECTOR with copies to the Director of Medical Education of the hospital. The format of the log may be patterned after that recommended by the Committee on Evaluation and Educational Standards of the AOCR or developed by the PROGRAM DIRECTOR.

   a. Documentation of outside training must conform to the format approved by the AOCR.

6. The RESIDENT shall be required to prepare one paper annually and send a copy to the secretary of the College.

7. IT IS RECOMMENDED THAT THE RESIDENT APPLY FOR CANDIDATE MEMBERSHIP IN THE AOCR DURING THE FIRST YEAR OF RESIDENCY.

8. The RESIDENT, AT THE INITIATION OF THE PROGRAM, SHALL RECEIVE A COPY OF THE PROGRAM SYLLABUS AND THE DOCUMENT OF MINIMAL STANDARDS FOR TRAINING IN DIAGNOSTIC RADIOLOGY.

Candidate Selection:

Candidates shall be graduates of Colleges of Osteopathic Medicine approved by the American Osteopathic Association.

2. Candidates shall be members in good standing of local, state and national osteopathic societies.

3. Candidates shall have completed at least one year of internship approved by the AOA.

4. Candidates shall exhibit the following qualities that are known to be requisite to the successful practice of the specialty of Diagnostic Radiology:

Candidates shall be well-motivated and well-rounded physicians, have a desire to read and keep abreast of the times in a rapidly changing specialty, an interest in research, and possess a broad philosophy of diagnosis and treatment of disease. This will preclude a narrow concept of diagnostic radiology. The candidate shall have an adequate understanding of the osteopathic concept.

5. Candidates shall be thoroughly grounded in the Code of Ethics of the AOA, which shall be a guide for them in their practice of Diagnostic Radiology.

VII. Educational Objectives:

The training program in Diagnostic Radiology is a full-time three-year residency. The educational objectives of this training program are as follows:

1. Basic and advanced training in Diagnostic Radiology at the postdoctoral level.

2. Certification by the American Osteopathic Board of Radiology.

3/26/75

MINIMAL STANDARDS FOR TRAINING IN RADIATION ONCOLOGY

I. Definition - The practice of Radiation Oncology consists of treatment of human disease by the use of roentgen rays, radium and natural and artificial radioactive substances.

II. Purpose of this Document

a. To establish minimal standards and requirements for specialty training in Radiation Therapy.

b. To encourage the highest standard of education and practice in the specialty of Radiation Oncology.

III. Duration of Training Period - The minimal training period in Therapeutic Radiology shall be three years.

IV. Approval - The training programs in Radiation Oncology come within the purview of the Committee on Postdoctoral training of the American Osteopathic Association and must also be approved by the Board of Trustees of the A.O.A.

V. Program Director

1. The chairman of the Department of Radiation Oncology may designate a responsible program director, nowever, this designation of authority does not relieve the department chairman from the responsibility of assuring that the Residency program meets or exceeds the recommended minimal standards.

2. The training program should be under the supervision of a full time Radiologist who is recognized as a specialist in Radiation Therapy.

3. He shall have at least three years of post residency experience in hospital Radiation Oncology.

4. He shall be a member of the American Osteopathic College of Radiology.

VI. Responsibilities of the Program Director

a. The program director shall be responsible to provide a complete training program in Radiation Oncology. This is not meant to imply that all training must be within the parent institution. Outside exposure of residents is encouraged, not discouraged. Acceptable procedures of satisfying deficiency in a training program may include:

1. An exchange program
2. Visitation program outside the parent hospital
3. College or University Course in Radiation Physics, Radiobiology, etc.
4. Other recognized courses or seminars

b. The program director shall register all residents with the secretary of the American Osteopathic Board of Radiology and the Secretary of the American Osteopathic College of Radiology.

c. The program director will notify the above named agencies in the event of change in status of the resident or training program.

d. The program director shall inform the secretary's of the A.O.B.R. and the A.O.C.R. of a residents successful completion of his program.

e. The program director will file annual reports with the Secretary of the Committee on Postdoctoral training of the American Osteopathic Association and Secretary of the A.O.C.R.

f. The program director will assure that the resident required papers are of an acceptable nature.

g. The program director shall be prepared to document the postdoctoral training of all Radiologists within the department since the time of the last inspection.

h. The program director will keep a copy of all required reports.

i. The program director will assure that the residents log and other records are maintained up to date.

VII. Department Requirements

a. The Radiation Oncology Department shall have an adequate record system for all cases in which consultation or therapy has been provided and a satisfactory pathologic cross file index using standard disease nomenclature.

b. The Department Library shall contain a sufficient number of current and established texts covering the fields of Radiation Therapy, Oncology, Radiology, Pathology and other current texts in general medicine and surgery in their various branches. The library will contain a reasonable number of appropriate and current journals related to this field (the radiology library should preferrably be housed within the department, rather than the general hospital library).

c. The department should be physically arranged to provide space and atmosphere condusive to resident study and conference.

d. Patient case load should be of sufficient magnitude to provide a broad experience in actual treatment and followup of the various types of cancer amenable to Radiation Therapy.

e. The Institution offering the Residency should have active programs in cancer surgery and cancer chemotherapy as well as in radiotherapy.

f. Radiation Therapy Equipment shall be of modern design and shall meet the requirements and standards of Federal, State or Local regulations. These include superficial, orthovoltage and supervoltage teletherapy. A sufficient amount of radium or its equivalent should be available along with a variety of applicators for both interstitial and intracavitary therapy.

g. A full time radiological physicist must be available.

VIII. Educational Program

a. Allied basic sciences - All Allied Basic Sciences pertinent to Radiation Therapy including Radiation Physics, Radiation Biology and Pathology with emphysis on neoplasm and medical statistics. Radiation Physics and Radiation Biology including treatment planning and dosimetry may be taught in the form of didactive lectures, seminars and practical laboratory excercises. These are to include training in basic radioisotope handling techniques (200 hours):

1. Radiation physics and instrumentation (100 hours)
2. Radiation protection (30 hours)
3. Mathematics pertaining to the use and measurement of radioactivity (20 hours)
4. Radiation biology (20 hours)
5. Radiopharmaceutical chemistry (30 hours)

b. Allied Clinical Fields - Paramount Allied Clinical Fields are diagnostic Radiology, Oncological surgery, and cancer chemotherapy. The resident should become familiar with the methods, techniques and results in these fields.

c. Patient material should be of sufficient magnitude to provide a broad experience in the actual treatment and followup of the various types of cancer ameanable to Radiation Therapy.

d. The resident should have experience in the actual use of all accepted common modalities of Radiation Therapy of the various types and locations of cancer.

e. The resident shall keep a log of his training program which shall be reported monthly to the program director with copies to the director of medical education of the hospital. The log shall include a statistical report of the work and activities of the resident as well as meetings attended, reading assignments, conferences, etc.

f. Documentation of training outside the parent institution must conform to the format approved by the A.O.C.R.

g. The resident shall be required to prepare one paper annually.

h. It is recommended that the resident apply for candidate membership in the A.O.C.R. during the first year of his residency.

i. The resident at the initiation of the program shall receive a copy of the program syllabus and document of minimal standards for training in Radiation Oncology.

IX. Candidate Selection

a. Candidate shall be graduates of College of Osteopathic Medicine approved by the American Osteopathic Association.

b. The candidate shall be members in good standing of local, state and National Osteopathic Society.

c. Candidate shall have completed at least one year of internship approved by the American Osteopathic Association.

d. The candidate shall be knowledgable of and abide by the ethics of the American Osteopathic Association.

X. Education Objectives

The training program in Radiation Oncology is a full-time three year residency. The education objectives of this program are as follows:

1. Basic and advanced training in Radiation Oncology on a post-graduate basis.

2. Certification by the American Osteopathic Board of Radiology.

MINIMAL STANDARDS FOR SPECIAL STUDY IN NUCLEAR MEDICINE

I. PURPOSE:

To identify and recognize an area of radiologic practice in which the knowledge and performance of nuclear medicine procedures are an extension beyond the practice of general radiology. Minimal requirements are proposed to qualify a physician for recognition of special competence in nuclear medicine.

II. OBJECTIVES:

To improve the quality of radiologic practice through additional study and experience gained with special training in nuclear medicine.

To establish a standard upon which individual competence can be developed and subsequently evaluated.

III. DEFINITIONS:

Nuclear medicine is that body of knowledge and special practice which requires the application of radioactive materials to the diagnosis and treatment of patients and the study of human disease.

IV. BASIC REQUIREMENTS OF A PROGRAM:

A. Institution. The training program must be carried out in an institution where a sufficient number of nuclear medicine procedures are performed.

The institution shall have an educational atmosphere with more than one training program functioning in postdoctoral studies. Application for intern and/or resident education is necessary.

B. Program Director. The Director of the training program shall be certified in nuclear medicine or other specialty with recognized competence in nuclear medicine.

The Director's credentials shall include specialized post doctoral training and evidence of continuing medical education, predominantly in the field of nuclear medicine.

C. Facilities. There shall be sufficient equipment of modern design to perform all nuclear medicine diagnostic procedures and the application of radionuclides for therapy in a competent, efficient, and safe manner.

Equipment should include, but not be limited to, rectilinear scanner, gamma camera of modern design, computer dedicated to nuclear medicine procedures, instrumentation for insuring

radiation safety, and adequate dose calibration, laboratory equipment dedicated to the usually performed clinical radioassay in vitro studies. Equipment dedicated to the performance of blood volumes, G.I. blood loss, fat absorption, hematologic procedures including ferrokinetics.

General facilities should include adequate space for interpretation of studies, consultation with other physicians, and audiovisual materials and an area for quiet study.

An intra-departmental library should be in the department containing current texts and journals related to nuclear medicine.

The program shall include cooperation and experience with the Department of Internal Medicine, Pathology and Surgery conducive to a broad knowledge and understanding of the utilization and performance of nuclear medicine.

V. QUALIFICATIONS WITHIN THE PROGRAM:

A. A ~~full~~ part-time Fellowship in Nuclear Medicine will be no less than one year of formal concentrated study.

B. A ~~part~~ full-time Fellowship or Preceptorship will include a minimum of three years which need not be continuous, but must represent an integrated educational program in Nuclear Medicine.

C. One year of concentrated study with a broad program covering the entire field of nuclear medicine.

D. An equivalent of three years of study which need not be continuous with adequate documentation of study, experience and achievement in preparation of radiopharmaceuticals with emphasis on quality control, evidence of understanding instrumentation for the measurement of radioactivity in practical applications directed toward radiation safety, dose preparation, radiation hazards, radiation safety protocols to be followed in case of radiation accidents, and the application of radionuclides in some area of biomedical research.

E. An original thesis suitable for publication upon completion of the program.

VI. EDUCATIONAL PROGRAM:

A. <u>Basic Science</u>. Evidence of formal course of study related to:

Basic radiation protection
Radiopharmacology
Instrumentation with emphasis on quality control
Radiation biology
Radiation physics
Clinical radioassay procedures

Radionuclide therapy, indications, treatment protocols and follow-up radionuclide applications in cardiology

B. General Requisites. Academic study and practical experience should be adequate to develop a thorough knowledge of nuclear medicine in the performance of the following:

General organ scanning techniques of brain, liver, spleen, lung, pancreas, thyroid, bone, kidney, heart, pericardium, cisterns.

Experience and formal training should be adequate to fulfill the requirements for NRC licensure.

Clinical radioassays including cortisol, digoxin, folates, TSH, B12, rennin.

Radioisotope tracer techniques to evaluate blood volumes, G.I. blood loss, ferrokinetics, fat absorption, T3, T4, TSH.

Adequate case documentation of treatment experience with I-131 for hyperthyroidism, thyroid carcinoma, P32.

Training should be adequate to prepare the candidate to operate a nuclear medicine department in a 300-500 bed general, non-training hospital.

Training program should be restricted to those institutions where at least one of the senior physicians administering the program is devoting at least 50% of his time to the practice of nuclear medicine.

C. Ancillary Parameters. Review and practical experience in the performance and correlation of diagnostic nuclear medicine procedures and there correlation with general radiology, computerized tomography and diagnostic ultrasound should be an integral part of the program.

D. Responsibilities. The student or candidate requisites should be such that will lend support to an educational program which should include at least the following:

1. Maintain a log identifying educational program, documentation of cases participated in and personally performed.

2. Evidence of active participation in teaching program for resident, interns, and students.

3. Formulation and preparation of original thesis based upon study and experience gained in the program.

E. Supplemental Education. There should be sufficient time allowed without detracting from the core program in order to gain additional experience in institutions recognized for their leadership in a subspecialty area of nuclear medicine,

such as cardiovascular, endocrine, neurologic, pulmonary or renal studies.

VII. APPROVAL:

A. Program:

1. Request for an approved program will be made on forms that will identify the following:

   a. Institution maintaining the program
   b. Credentials of responsible Program Director
   c. Departmental volume statistics
   d. Facilities and equipment data
   e. Outline of proposed educational program

2. The above information must be submitted to the Committee on Evaluation and Educational Standards of the American Osteopathic College of Radiology and the Committee on Postdoctoral Education of the American Osteopathic Association.

B. Student:

1. Must have had an A.O.A. approved internship.

2. Must have a minimum of two years formal (resident) postdoctoral training beyond internship in an A.O.A. approved program covering the basic fundamentals of radiology.

3. Application for Fellowship shall be made on an official form and in advance of the training experience.

4. Upon completion of the approved training program an annual report of the Program Director and an annual report of the Fellow including documented cases shall be submitted for approval of the training experience. For part-time Fellowships, annual reports for each yearly interval are to be submitted.

5. Until January 31, 1979, individuals meeting the aforementioned criteria of these "Minimal Standards", but who have already completed their studies, May upon submission of all information required, be considered for and receive approval.

MHS:ff
3/26/78

ATTACHMENT NO. 4

HOW TO INITIATE A RESIDENCY

1. Secure approval of the hospital governing body who is responsible for the overall program.

2. Secure approval of the Staff in embracing a teaching responsibility.

3. Establish a residency training program considered current with todays concepts. In the event the training program is not complete, document the methods by which the program will be complete for example (e.g. exchange lectures, special courses, special lectures and courses, exposures to procedures and methods not provided in the parent hospital, etc.)

4. Submit the training program to:

   A. Those responsible for the teaching in the hospital (Intern-resident committee. Medical Education Directors, Department heads, etc.

   B. The committee of Postdoctoral Training after obtaining an application form from the Office of Hospital Affairs of the A.O.A. (applications for new residencies are received by the C.O.P.T. in January of each year.)

   C. The Evaluating and Education Committee of the A.O.C.R. for evaluation and recommendations to the C.O.P.T. of the A.O.A.

   D. The A.O.C.R. for informational purposes and hopefully approval

   E. The A.O.B.R. for informational purposes.

5. The X-ray Department must have sufficient professional and allied personnel in the department to conduct a residency and to operate independent of the presence of residents.

6. Make sure that the professional persons in the department wish to assume the responsibility of a training program, i.e. to teach, encourage and develop radiologists.

7. Make sure that there is space for the resident in the professional area of the department, e.g. a desk and a chair or some suitable place for him to study other than the library. Provide adequate viewing box space so that the resident may study cases and films preferably without interferring with the normal functioning of the department.

8. The department library must have sufficient current books and journals for residency training.

GUIDELINES FOR STARTING A RESIDENT IN TRAINING

1. Carefully screen applicants for motivation, interest and potential as a radiologist insofar as such may be possible.

2. Check references carefully by letter and also by personal communications whenever possible.

3. Interview the potential resident and outline the training program and the training period indicating what portion of the program may have to be taken outside the hospital is indeed such is the case.

4. State policy regarding a 3 year program, (subject to annual renewal during this period of time) and also discuss the possibility of more than 3 years being required for preparation of a resident for recommendation for examination and board certification.

5. If exchange residency experience is required or if there is work to be taken outside the institution discuss with the resident the time periods involved, the expenses concerned, etc. These might include:

   a. Special courses in radiophysics and radiobiology.

   b. Special course at Armed Forces Institute of Pathology.

   c. Special work in cobalt or with high energy sources.

   d. Special work at Children's Hospital for pediatric radiology.

   e. Special work at a neurological center for neuroradiology.

   f. Special work in angiography if needed.

   g. Special work in radium and/or brachy therapy if needed.

6. Discuss attendance at conventions and other radiological meetings and courses e.g. A.O.C.R., Roentgen Ray Society, Radiological Society of North America, Special Courses of interest such as are put on by various university groups in Florida, Kentucky, Ohio, Michigan, New York, etc. as may be deemed appropriate.

7. Make it clear that the resident is on probation for periods or increments of 3 months during the first year and subject to review and decision for continuing at the discretion of those responsible for training. Likewise the hospital and the department are on probation with the beginning resident who may indeed wish for good sufficient reason, to terminate his residency at least during the first year. It should be made clear that the resident must be recommended to the hospital administration for continuance in the residency on a annual basis.

HOW TO INITIATE A RESIDENCY

8. Set up a quarterly reporting system by the trainor to the administration and or the Medical Educational Director indicating special assignments, if any, conditions to be met during the coming quarter if any and in summary indicate that the resident is aware of his strength and his weakness and is current on all aspects of his training. This should include his strength and weaknesses in his progress and including whether or not his training may require more than 3 years. A copy of this quarterly report is to be filed in the resident's log as well as in the Administrator's Office and or the office of the Medical Educational Director.

9. Suggest early in the resident's training that thought be given to the topic for a paper which is required by the American Osteopathic Board of Radiology as part of his qualification for examination -- give all proper aid and assistance with such a paper.

10. The resident is required to prepare a yearly paper or treatise on subjects of current interest. Use this technique to teach the resident in the art of thought, organization, presentation outline and eventually medical writing.

11. As soon as a resident has begun his training propose his name for candidate status in the A.O.C.R. and write the appropriate letters of recommendation for such application to the Secretary of the American Osteopathic College of Radiology.

12. Keep the College Secretary and the Board Secretary appraised of the resident's progress at least annually.

13. At the beginning of the resident's final year, communicate with the Secretary of the A.O.B.R. to be sure that all steps necessary for his consideration as an examinee are met.

14. The resident's application for examination by the American Osteopathic Board of Radiology should be made to the Secretary of the American Osteopathic Board of Radiology before September 1st of the year prior to the examination. Examinations are administered annually, during March or April at the headquarters of the American Osteopathic Association in Chicago or at such other location designated by the A.O.B.R.

ATTACHMENT NO. 4

9) If more than one inspector is assigned to an on-site evaluation, one inspector who fulfills all the qualifications should be designated as senior, or chief inspector. His assistant then need not necessarily meet all the basic requirements, such as the minimum of five years of organizational experience in his own hospital, the A.O.C.R. or A.O.B.R. The inspection trip or trips might then serve as working experience to qualify as a fully qualified inspector. However, the criteria of certification and association with a residency training program which has not been cited for serious deficiency should be required for an assistant inspector.

10) Inspector's qualifications should be reviewed and approved by a designated procedure within the A.O.C.R., possibly by the Education and Evaluating Committee and subsequently by the Board of Directors, prior to recommendation to the A.O.A.

RADIOLOGY Va
Facilities and
Statistical Data

Date_____

DIAGNOSTIC RADIOLOGY EQUIPMENT:
(List number of units in each
institution available to residents)

Radiographic Units (Wall
Radiographic Fluoroscopic Units
Image Intensifiers:
Mirror Image
T.V. Equipped
Film Units
T.V. Tape Units
Bony Section Units
Special Head Units
Rapid Cassette or Film Changers
Mobile Units
Other (Specify)

DIAGNOSTIC RADIOLOGY

Total patients examined
Total diagnostic examinations

Routine examinations of:
Head
Chest
Abdomen
Spine
Extremities

Examinations employing contrast media:
Alimentary Tract:
Esophagus only
Upper G.I. series
Small intestine
Colon
Gall bladder
Cholangiography
Other (Specify)

RADIOLOGY Vb
Facilities and
Statistical Data

Date_____

DIAGNOSTIC RADIOLOGY - CONT.

Genitourinary Tract:
Cystoscopy programs
Retrograde programs
Urograms
Urethrograms
Pyelocystography
Other (Specify)

Angiocardiograms*
Aortograms*
(use separate sheet if necessary)
Arteriograms (selective) of:*
Head and Neck
Extremities
Venograms (selective) of:
Vena Cava
Extremities
Other
Lymphangiograms*
Mammograms*
Bronchograms*
Arthrograms*
Sialograms
Myelograms*
Ventricular gas studies*

Sonograms*
Other type special studies* (specify)

* Spec: whether procedure is performed by X-Ray Department or Clinician.

RADIOLOGY Vc
Facilities and
Statistical Data

Date_____

THERAPEUTIC RADIOLOGY EQUIPMENT:
(If not present, please attach documentation of facilities data from outside affiliated institution.)

Superficial Units (140 KV or less)
Orthovolt Units (200-400 KV)
Megavoltage (1 Mev, or over)
Gamma Teletherapy
Simulator
Radium or Radium Substitutes (total amount available, general form, etc.)

Other (specify)

THERAPEUTIC RADIOLOGY:

Total patients seen in consultation
Patients accepted for treatment
Follow-up Visits
Total treatments with:
Superficial
Orthovoltage
Megavoltage
Gamma Teletherapy
Radium or radium substitutes:
Surface application
Intracavitary
Interstitial

Total treatments by all methods

RADIOLOGY Vd
Facilities and
Statistical Data

Date_____

NUCLEAR MEDICINE

Please document outside source of training if not carried out in Radiology Department.

A. Diagnostic Equipment - probes, monitors, scalers etc. (list)

Make	Type	Age

B. Scanning Equipment - linear, camera. (list)

C. Are there A.E.C. materials and use licenses available? Do examinations performed comply with the limitations of the licenses?

RADIOLOGY VIc
Program

Date_____

E. Radiation Safety Standards:

1. Is all radiation equipment calibrated to meet the National Standards? _____

Give the date of last report _____

By whom and what agency___ _____

_____

2. Do all radiation emitting devices conform to acceptable standards? (i.e., filtration, collimation, timing, etc.) _____

Briefly describe any inadequacies:

3. What is the method of personnel monitoring?

How often are reports made?_____
Is there evidence of over-exposure_____
If yes, explain:

4. Are all radiation protective devices (control booths, barriers, aprons, gloves, etc.) readily available and in use? Yes___ No___

5. Are radiation exposure records:
part of the consultation report Yes___ No___
part of the department record Yes___ No___
Are accumulative dosage records for the patients kept? Yes___ No___

CHART REVIEW FOR RESIDENCY INSPECTION

Review of at least two cases in each subcategory.

A. DIAGNOSTIC

Cases should come from pathologic index file during past [illegible]

1. In the average, are the radiographic examinations [illegible]_____
fair_____, poor_____

2. Are the procedures complete and adequate for board training of the resident in basic fundamentals as well as special procedures?

Yes_____ No_____

B. THERAPY

Therapy cases should come from department records.

X-Ray or Cobalt - Chest neoplasm
Abdominal neoplasm
Benign inflammatory
superficial malignancy

Radium - intracavitary - uterus
cervix

Interstitial

1. Are therapy records complete and up-to-date for retrospective review by the resident in training? Yes___ No___ If no, explain:

2. Is there evidence of Radiology resident's participation or observation in the therapy case records?

Yes_____ No_____

RADIOLOGY VIIa
Hospital Medical Records

Date_____

CHART REVIEW FOR RESIDENCY INSPECTION

Review of at least two cases in each subcategory. Patient discharged with the following final diagnosis.

MEDICAL

A.	Cardiopulmonary	Pulmonary infarction pneumonia pleuritis valvular heart disease
B.	Gastrointestinal	gastritis gastric or esophageal hemorrhage
C.	Urinary tract	pyelonephritis renal cystic disease renal or ureteric calculi
D.	Osseous	fracture (hospitalized) metabolic disease
E.	Neurological	vascular - C.V.A. Brain Tumor Thrombophlebitis

SURGICAL

A.	Cardiopulmonary	lung resection pulmonary neoplasm cardiac surgery
B.	Gastrointestinal	gastrectomy colon resection
C.	Urinary tract	kidney neoplasm bladder neoplasm
D.	Osseous	amputation resection - laminectomy open reduction
E.	Neurological	vascular - traumatic skull endarterectomy venous ligation

SPECIAL USES:

Three cases of each category - hospitalized

A. Radium - intracavitary - uterus
cervix

B. X-Ray or Cobalt therapy - chest
abdomen

RADIOLOGY VIIb
Hospital Medical Records

Date_____

CHART REVIEW FOR RESIDENCY INSPECTION - CONTINUED

1. Do the medical records reflect the level of respect for the Department of Radiology? High_____ Medium_____ Low_____

2. Is there evidence of correlation of the radiographic findings? Yes___ No___

3. Are the medical records conducive to the educational program of the residents in Radiology? Yes___ No___

INSPECTION REPORT

_____ _____

(Date of Inspection) (Hospital)

TYPE OF INSPECTION:

Intern Training_____

Residency Training_____

INSPECTORS SPECIALTY OR AREA

RECOMMENDATIONS OF THE INSPECTORS TO THE COMMITTEE ON POSTDOCTORAL TRAINING:

SUMMARY: (To be completed on separate sheet and shall include the following:)

1. Summary sheet to be written by team captain reflecting the overall evaluation of the inspection, as determined by the entire team in a critique.

2. Complete Inspection Outline provided by the Committee on Postdoctoral Training.

3. Report any other findings pertinent to inspection.

REQUIREMENTS AND RECOMMENDATIONS

_____
Hospital

_____
Specialty or Area

_____
Date

I. Requirements that have not been met. (Refer to Minimum Standards)

II. Recommendations:

III. Inspector's Recommendation:

1. Should this program be approved? Yes_____ No_____
2. Number of residencies requested: _____
   Number of residencies recommended for approval: _____
3. Summary sheet should reflect findings in the inspector's opinion that recommends approval or denial.

SUMMARY

_____ _____

(DATE) (HOSPITAL)

RADIOLOGY IV
Identification Data

Date_____

1. Hospital_____

2. Name of Department Chairman_____

3. Date of most recent inspection (Radiology Residency)_____

4. Number of residents approved immediately prior_____

   Number of residents requested this inspection_____

   New Application _____ Date submitted _____

5. Name of individual responsible for the training program_____

   _____

6. Professional personnel. (List names, degree, certification, level, post-graduate training since last inspection)

7. Residents in training. (List names, degree, year of training)

Date_____

A. Personnel:

1. Clerical personnel

2. Technical personnel

Are there adequate clerical and technical personnel for patient volume?

B. Department Records:

1. Indicate the type of records kept. (These should be available for inspection.)

2. Are the methods of recording and retrieving records adequate?

3. Pathology Cross Index:

Are all cases examined, indexed for pathology?
Indicate the method (form) for pathology cross index.

ATTACHMENT NO 4

Date: _____

DIAGNOSTIC RADIOLOGY EQUIPMENT:
(List number of units in each institution available to residents)

Radiographic Units Only
Radiographic Fluoroscopic Units
Image Intensifiers:
- Mirror Image
- T.V. Equipped
- Cine Units
- T.V. Tape Units

Body Section Units
Special Head Units
Rapid Cassette or Film Changers
Mobile Units
Other (Specify)

DIAGNOSTIC RADIOLOGY

Total patients examined
Total diagnostic examinations

Routine examinations of:
- Head
- Chest
- Abdomen
- Spine
- Extremities

Examinations employing contrast media:
Alimentary Tract:
- Esophagus only
- Upper G.I. series
- Small intestine
- Colon
- Gall Bladder
- Cholangiography
- Other (Specify)

ATTACHMENT NO. 4

Date_____

DIAGNOSTIC RADIOLOGY - CONT.

Genitourinary Tract:
- Excretory urograms
- Retrograde urograms
- Cystograms
- Urethrograms
- Hysterosalpingograms
- Other (Specify)

- Angiocardiograms*
- Aortograms*

(use separate sheet if necessary)

Arteriograms (selective) of:*
- Head and Neck
- Extremities

Venograms (selective) of:
- Vena Cava
- Extremities
- Other

- Lymphangiograms*
- Laryngograms*
- Bronchograms*
- Arthrograms*
- Sialograms
- Myelograms*
- Ventricular gas studies*

- Mammograms*
- Other type special studies* (specify)

* Specify whether procedure is performed by X-Ray Department or Clinician.

Date_____

THERAPEUTIC RADIOLOGY EQUIPMENT:
(If not present, please attach documentation of facilities data from outside affiliated institution.)

Superficial Units (140 KV or less)
Orthovoltage Units (200-400 KV)
Megavoltage (1 Mev. or over)
Gamma Teletherapy
Simulator
Radium or Radium Substitutes (total amount available, general form, etc.)

Other (specify)

THERAPEUTIC RADIOLOGY:

Total patients seen in consultation:
Patients accepted for treatment
Follow-up Visits
Total treatments with:
- Superficial
- Orthovoltage
- Megavoltage
- Gamma teletherapy
- Radium or radium substitutes:
  - Surface application
  - Intracavitary
  - Interstitial

Total treatments by all methods:

ATTACHMENT NO. 4

Date_____

NUCLEAR MEDICINE

Please document outside source of training if not carried out in Radiology Department.

A. Diagnostic Equipment - probes, monitors, scalers, etc. (list)

Make	Type	Age

B. Scanning Equipment - linear, camera. (list)

C. Are there A.E.C. materials and use license available? Do examinations performed comply with the limitations of the license?

Date_____

A. NUCLEAR MEDICINE - DIAGNOSTIC

1. Number of patients _____
2. Number of laboratory procedures _____
3. Number of image procedures _____

Bone	_____
Brain	_____
Kidney	_____
Liver	_____
Lung	_____
Pancreas	_____
Thyroid	_____
Other	_____

TOTAL OF ALL NUCLEAR DIAGNOSTIC PROCEDURES _____

B. NUCLEAR MEDICINE - THERAPY

a. Number of patient clinical exams (Follow-up, re-check, consultation) _____
b. Number of patients treated _____
c. Number of treatments given _____
d. List type, material, number of each _____

TOTAL OF ALL NUCLEAR THERAPEUTIC PROCEDURES _____

Date_____

A. General Program:

1. Is this a total program supplied within the department? Yes____ No____

   a. If not, please supply documentation of supplemental training outside the department.

   b. Review the recorded Resident Program as submitted by the trainer.

2. Explore the teaching philosophy of the trainer as well as others connected with the residency program.

3. Is there evidence of periodic evaluation of the educational progress of the trainee?

4. Is there evidence of continuing interest and motivation of both the trainer and trainee?

5. Is there evidence of progressive and continuing responsibility by the trainee in his training as his term progresses?

6. Are the department library facilities adequate? Is the department library integrated into the hospital library or is it separate? If it is separate, is it adequate or limited in scope?

7. What is the method of instruction in the basic sciences and correlation with clinical medicine?

8. Is there evidence of cooperative assistance in the training of the resident by the departments of Pathology, Medicine, and Surgery?

   a. Is the conference system used for inter-departmental education?

ATTACHMENT NO. 4

Date_____

9. What facilities are available for teaching, slides, projectors, tape recorders, etc.? Is medical photography utilized in this department and to what extent?

10. Is there evidence that the resident attends autopsies? Yes____ No____

11. Is there evidence of training in the clinical application of nuclear medicine? Yes____ No____

12. Ask the trainer what areas of his residency training program are unsatisfactory to him.

B. Resident Interview:

1. Is the resident satisfied with his program to date?

2. Does the resident perform on his own or under supervision?

3. Does the resident participate in the training of interns, undergraduates, educational programs, or staff education? Yes___ No____

4. Does resident help maintain museum cases and pathologic cross index?

B. Resident Interview (Cont.)

5. Does the resident attend and participate in the following:

	YES	NO
a. Staff meetings		
b. Tumor Board meetings		
c. Mortality Review meetings		
d. Medical Audit Committee meetings		
e. Clinics-Pathologic conferences		
f. Department Educational meetings		

6. Does the resident have any suggestions that would improve his training program?

C. Review of the Resident's Log:

1. Is there evidence of periodic evaluation of the educational progress of the trainee?

2. Does the log adequately reflect the progress and academic exposure of the resident?

3. Is there documentation in the log reflecting the statements discussed in the resident interview?

D. Exchange and/or Supplementation Program:

1. Briefly describe where and to what extent (time) spent in education outside the institution.

2. Is the supplemental program under the direction and supervision of the trainer?

3. Does the exchange and/or supplemental education program fully complement and complete the basic program to be approved?

Date_____

E. Radiation Safety Standards:

1. Is all radiation equipment calibrated to meet the National Standards? _____

   Give the date of last report _____

   By whom and what agency_____

   _____

2. Do all radiation emitting devices conform to acceptable standards? (i.e., filtration, columnation, timing, etc.) _____

   Briefly describe any inadequacies:

3. What is the method of personnel monitoring?

   How often are reports made?_____
   Is there evidence of over-exposure_____
   If yes, explain:

4. Are all radiation protective devices (control booths, barriers, aprons, gloves, etc.) readily available and in use? Yes____ No____

5. Are radiation exposure records:
   part of the consultation report Yes____ No____
   part of the department record Yes____ No____
   Are accumulative dosage records for the patients kept? Yes____ No____

ATTACHMENT NO. 4

Date_____

CASE REVIEW FOR RESIDENCY INSPECTION

Review film studies of at least one case in each subcategory.

A. DIAGNOSTIC

Cases should come from pathologic index file during past one to two years.

1. On the average, are the radiographic examinations good_____, fair_____, poor_____?

2. Are the procedures complete and adequate for board training of the resident in basic fundamentals as well as special procedures?

Yes_____ No_____

B. THERAPY

Therapy cases should come from department records.

X-Ray or Cobalt - Chest neoplasm
Abdominal neoplasm
benign inflammatory
superficial malignancy

Radium - intracavitary - uterus
cervix

interstitial

1. Are therapy records complete and up-to-date for retrospective review by the resident in training? Yes____ No____ If no, explain:

2. Is there evidence of Radiology resident's participation or observation in the therapy case records?

Yes_____ No_____

ATTACHMENT NO. 4

Date_____

CHART REVIEW FOR RESIDENCY INSPECTION

Review of at least two cases in each subcategory. Patient discharged with the following final diagnosis.

MEDICAL

A.	Cardiopulmonary	Pulmonary infarction pneumonia pleuritis valvular heart disease
B.	Gastrointestinal	gastritis gastric or esophageal hemorrhage
C.	Urinary tract	pyelonephritis renal cystic disease renal or ureteric calculi
D.	Osseous	fracture (hospitalized) metabolic disease
E.	Neurological	vascular - C.V.A. Brain Tumor Thrombophlebitis

SURGICAL

A.	Cardiopulmonary	Lung resection pulmonary neoplasm cardiac surgery
B.	Gastrointestinal	gastrectomy colon resection
C.	Urinary tract	kidney neoplasm bladder neoplasm
D.	Osseous	amputation resection - laminectomy open reduction
E.	Neurological	vascular - traumatic skull endarterectomy venus ligation

SPECIAL CASES:

Three cases of each category - hospitalized

A. Radium - intracavitary - uterus
cervix

B. X-Ray or Cobalt therapy - chest
abdomen

Date_____

CHART REVIEW FOR RESIDENCY INSPECTION - CONTINUED

1. Do the medical records reflect the level of respect for the Department of Radiology? High_____ Medium_____ Low_____

2. Is there evidence of correlation of the radiographic findings? Yes____ No____

3. Are the medical records condusive to the educational program of the residents in Radiology? Yes_____ No_____

. . . . . .

ATTACHMENT NO. 4

REGISTRATION

Registration Fee - $240 payable to AOCR

Residents, Interns, and Students may attend without fee if preregistered. Registration should be accompanied by a letter from Chief Trainer, D.M.E. or Dean.

Residents should obtain Reading List from Dr. Willman prior to Course.

REGISTRATION

Name _____

Address _____

City _____

State _____ Zip _____

A.O.A. Number _____

Osteopathic College _____

Year _____

Mail To: Michael K. Willman, D.O.
Secretary, American Osteopathic
College of Radiology
800 West Jefferson
KIRKSVILLE, MO 63501

ATTACHMENT NO. 4

PROGRAM

Thursday, January 25, 1979

8:00 a.m. Radiation Safety

9:00 a.m. Personnel Monitors

10:00 a.m. N.C.R.P. Reports

11:00 a.m. Federal, State, Local and Hospital Codes

12:00 LUNCH

1:00 p.m. To 4:00 p.m. Review and Quiz Sessions

4:00 p.m. Review Exam

5:00 p.m. COURSE ENDS

SPEAKERS

Theodore Fields, M.S.

Charles R. Griffith, M.S., F.A.C.R.
Chicago College of Osteopathic
Medicine
Chicago, Illinois

THE AMERICAN OSTEOPATHIC COLLEGE OF RADIOLOGY

Presents

The Physics of Nuclear Medicine

January 23, 24, 25, 1979

SHERATON-SAND KEY HOTEL
CLEARWATER BEACH, FLORIDA

PROGRAM

Tuesday, January 23, 1979

7:30 a.m.	Registration
8:00 a.m.	The Atom & Nucleus
9:00 a.m.	Radioactivity
10:00 a.m.	Units & Constants
11:00 a.m	Decay Schemes of Clinically Useful Radioisotopes
12:00	LUNCH
1:00 p.m.	Interaction of Radioisotopes with Matter
2:00 p.m.	Dosimetry of Nuclear Medicine
3:00 p.m.	Principles of Radiation Detection
4:00 p.m.	Scintillation Detectors
5:00 p.m.	ADJOURN

SEND HOTEL RESERVATION CARD DIRECTLY TO HOTEL AT LEAST 30 DAYS PRIOR TO COURSE

PROGRAM

Wednesday, January 24, 1979

8:00 a.m.	Basics and Practical Electronics
9:00 a.m.	Scanners, Cameras, and Other Imaging Devices
10:00 a.m.	Principles and Practices of In-Vitro Counting
11:00 a.m.	Principles and Practices of In-Vivo Imaging
12:00	LUNCH
1:00 p.m.	Statistics
2:00 p.m.	Quality Control and Equipment Evaluation
3:00 p.m.	Collimators
4:00 p.m.	Emission and Transmission Computed Tomography, NMR Imaging
5:00 p.m.	ADJOURN

(Continued)

COCKTAIL RECEPTION

Compliments of Kodak

Thursday, 6-7 p.m.
January 25, 1979

Program Submitted to A.O.A. for 24 credit hours

For N.R.C. Requirements you must seek approval on an individual basis

Program Director

George O. Faerber, D.O.
Committee on Continuing Post-Graduate Education

George O. Faerber, D.O., Chairman

Anthony Bascone, D.O.
John Agnew, D.O.
Fred Katz, D.O.
Michael Podolsky, D.O.
Wesley Boudette, D.O., Dean

1481

PHYSICS OF THERAPEUTIC NUCLEAR MEDICINE
AND RADIOLOGY

TUESDAY January 13		Background of Radiation Therapy
7:00 A.M.	A1	Basic Physics Energy, Radiation, Spectra
8:00 A.M.	A2	Atomic and Nuclear Physics Atoms, Nuclei, Radioactivity
9:00 A.M.	A3	Production of X-Rays Theory, Tubes
10:00 A.M.	A4	Electrical Sources X-Ray, Accel, Generators, Betatrons
11:00 A.M.	A5	Teletherapy Units Cobalt, Cesium
12:00 Noon		Discussion LUNCHEON
1:00 P.M.	A6	Sealed Sources Radium, Cesium, Gold, Radon, Strontium, Californium, Irridium-19, Iodine 125
2:00 P.M.	A7	Interaction of X and Gamma with Matter Photo, Compton, Paid Prod.
3:00 P.M.	A8	Basic Principles of Radiation Biology Ion, LET, Oxygen, Hit, Cells, NSD
WEDNESDAY January 14		Practice of Radiation Therapy
7:00 A.M.	B1	Principles of Radiation Oncology and Cancer Radiotherapy
8:00 A.M.	B2	Treatment Planning Fixed field modalities, Iso dose
9:00 A.M.	B3	Treatment Planning Rotation, Multiple

10:00 A.M.	B4	Treatment Planning Breast, Hodgkins, Special, Computer
11:00 A.M.	B5	Treatment Planning-Sealed Sources Radium, Cesium, Strontium
12:00 Noon		Discussion LUNCHEON
1:00 P.M.	B6	Treatment Planning-Superficial
2:00 P.M.	B7	Radioactive Isotopes in Therapy I-131, P32, Au-198
3:00 P.M.	B8	Problems & Pitfalls in Radiation Therapy
THURSDAY January 15		Safety in Radiation Therapy
7:00 A.M.	C1	Measurement of Radiation Thimble chambers, Survey meters, TLD, Calibrations
8:00 A.M.	C2	Radiation Safety - X-ray Shielding, Time, Distance, Surveys, Periodic Tests
9:00 A.M.	C3	Radiation Safety-Radioactivity Receipt, Storage, Usage, Surveys, Checks
10:00 A.M.	C4	Establishment of a Radiation Therapy Facility Design, Equipment selection, Staffing, Licensing, Certificate of Need
11:00 A.M.	C5	CRT Image Recording
12:00 Noon		CRT Discussion LUNCHEON
1:00 P.M.	C6	Review
2:00 P.M.	C7	Written Quiz
3:00 P.M.	C8	Review Quiz

REFERENCES

1. Meredith, W.J. and Massey, J.B. "Fundamental Physics of Radiology." Williams & Wilkens, Baltimore, 1972.

2. Johns, H.E. and Cunningham, J. "The Physics of Radiology." C.C. Thomas, Springfield, IL 1978.

3. Ruben P, et.al. "Clinical Oncology" 4th Edition, Un. of Rochester, Rochester, NY 1974.

4. Selman, F. "The Basic Physics of Radiation Therapy," C.C. Thomas, Springfield, IL 1960.

5. Cohen, M. and Martin, S.J., "Atlas of Radiation Dose Distributions" I AEA, Vienna, 1966.

AOCR Passes New Minimal Standards For Residency Training In Las Vegas

The American Osteopathic College of Radiology (AOCR) approved new minimal standards for residency training in diagnostic radiology and revised minimal standards for residency training in radiology at the October annual meeting held in Las Vegas. It had become obvious to many members of the College that the previous minimal standards which required three months training in radiation therapy represented precious time that could be better devoted to increasing demands of pediatric radiology, ultrasound, computerized axial tomography, and vascular radiology. There was never a question that three months training in radiation therapy would result in a trained radiation oncologist, but this requirement persisted primarily because of sheer inertia mixed with a tinge of sentiment to retain the old. Certainly, in most osteopathic hospitals supervoltage therapy is not available. Consequently, the resident spent three months outside of the institution, which in addition to other time outside the parent hospital such as AFIP, created no great sense of enthusiasm among program directors, radiology staff, or hospital administration. In fact, it may well be the obvious absence of radiology residents from the parent hospital for long periods of time that causes administration to deny requests for increasing the number of radiology residents. Finally, the resident reviewing the three months rotation in radiation therapy realizes that, in the quest for a position as a staff radiologist, such a three month period may well have been better spent in ultrasound, vascular radiology, or CT scanning. If radiation oncology is desired as a subspecialty, there are AOA approved three-year residencies available for such training in our profession.

There has also been misunderstanding by the NRC. The AOCR mainly intended that the three months in radiation therapy was primarily to expose the resident to the fundamentals of radiation oncology as a discipline to be applied in the early diagnosis, adequate treatment and follow-up of the cancer patient. This three-month rotation is still retained in the revised minimal standards for residency training in radiology, primarily for the above reason, in those hospitals that have radiation oncology departments and to allow the resident to determine degree of interest in the future specialty practice of radiation oncology. If you still have concern regarding these changes, please re-read Dr. Andrews' excellent overview in the August 1979 issue of VIEWBOX.

The following requirements were added to both programs: 1 month in computerized axial tomography, 2 months in pediatric radiology, and the recommendation that the 3-month rotation in nuclear medicine be of such caliber so as to qualify the resident for licensure by the NRC. In point of fact, the hospital residency inspectors will anticipate that the resident has been added to the hospital NRC license. An NRC license will certainly allow the resident to better compete for available positions.

The approved new minimal standards have been submitted to COPT for consideration at the November meeting and if approved, will then be submitted to the Board of Trustees for final AOA approval. At such time, the program director of a presently approved radiology residency program may submit a new program for three-year residency training in diagnostic radiology to Dr. Ward, Executive Director of the AOA Bureau of Education, with a copy to Dr. Willman, Secretary of the College. Such program will then be submitted to the AOCR Committee on Evaluation and Educational Standards for approval. Approval will not require an on-site inspection if there is a currently approved residency training program in radiology. The program director will then have the choice of offering either program to a prospective applicant. Residents in present radiology residency programs would continue to completion, unaffected by any change. Assuming approval by COPT and AOA Board of Trustees, a straight three-year diagnostic radiology residency program would probably not take effect till January or July of 1981. This represents recognition by the College of the increased demands of the state of the art of imaging procedures, pediatric, vascular, and interventional radiology.

MR. CUNNINGHAM: Dr. Blahd, on behalf of the American Board of Nuclear Medicine.

DR. BLAHD: Thank you, Mr. Chairman and members of the committee.

I wanted to make a statement on behalf of the American Board of Nuclear Medicine. This statement has been forwarded to you, and I presume distributed to the committee and, of course, it has to do with the licensure for therapeutic administration of radioactive materials.

The American Board of Nuclear Medicine recommends that physicians certified by the board as specialists in nuclear medicine be recognized by the Nuclear Regulatory Commission as having satisfied its requirements for licensure for therapeutic use of unsealed sources of radioactive materials in categories IV and V in the Regulatory Guide 10.8, for the following reason:

Training and experience in the therapeutic use of radionuclides in a required two-year residency programs approved by the Liaison Committee on Post-Graduate Medical Education, and leading to certification by the American Board of Nuclear Medicine, meet or exceed the Nuclear Regulatory Commission requirements. A recent survey by the board of required two-year residency training programs indicates that these programs provide approximately 125 to 350 experiential and instructional hours in the diagnosis, treatment and management of therapy patients, and these programs, averaged over a two-year period,

experienced with approximately 150 therapy patients, roughly 120 patients with hyperthyroidism, and 20 to 25 patients with thyroid cancer. That substantially exceeds the requirements in the Nuclear Regulatory Commission Regulatory Guide 10.8, Appendix A.

Furthermore, the American Board of Nuclear Medicine certification, which is a seven-hour, 250 objective type question examination, devotes 22 percent of its questions on basic science and therapy application, and more than 6 percent of the questions specifically to therapy of radioactive materials.

Therefore, since the residency training programs approved by the Liaison Committee in Graduate Medical Education, leading to American Board of Nuclear Medicine certification, provides training in therapeutic use of radioactive materials, and since these programs provide experience in diagnosis, treatment and management of therapy patients in numbers that exceed those required at NRC's Regulatory Guide 10.8, and since the American Board of Nuclear Medicine specifically certifies its Diplomates by examination in therapeutic use of unsealed sources, and is the only certified board that issues a special certification -- I have asked that a sample of our certificate be distributed to the committee -- it is the contention of the board that its Diplomates are qualified to be licensed for the therapeutic use of unsealed sources of radioactive materials, and should be so recognized by the Nuclear

Regulatory Commission.

Thank you, Mr. Cunningham, for allowing me to make these comments, and I will try to deal with any questions.

MR. CUNNINGHAM: Thank you, Dr. Blahd.

Questions from members of the committee?

Dr. Walker wants to make a comment.

DR. WALKER: We have reviewed the information that you sent in. The Staff had a comment, and that was that most of the administrations we see concern the use of P-32 in soluble form. We notice that in your submission you say that many of the programs don't include this any more as a modality that is not in current use, and I notice Dr. Griem has said that some of this is now coming back into favor.

We were a little concerned that some of the problems here could be headed off, and I think the statements by the Staff were such as one simple solution to something of this type would be to include specific training, such as laboratory clinical experience without the actual administration, but to include at least such things as specific training and what the different solutions look like, how they are applied, and some of the radiation safety procedures which are quite different for the P-32 compounds and many of the other ones, and how these are applied. We don't see this in any training programs, and it's one of the things that concerned us.

DR. BLAHD: Well, this review of some 22 training programs was just done. It appears that during a year's time there were only 29 procedures done for malignant effusions in this entire group, and only eight of the 22 programs actually had this kind of activity go on in the program.

My feeling is that these procedures, with the use of chromic phosphate and P-32 are not as widely done as they used to be, and I would believe that instructions that you are suggesting as to the use of these compounds, their appearance, their metabolism and so on, might be sufficient in those programs where these procedures are not widely done.

I think the board is most concerned with the management of patients with hyperthyroidism and cancer, but on the other hand, it would also like to be able to include these other procedures, even though they are not widely used.

MR. CUNNINGHAM: Dr. Griem?

DR. GRIEM: What concerns me is a little bit of what--the depth of the training in radiation biology, particularly when one starts to deal with potentially lethal damage, sub-lethal damage, slow repair, and many of the things that are in the therapy radiation biology program. And in particular, when one considers that cancer treatment no longer is single modality, but multi-modality, and involves adriomycin which may effect sublethal repair. The question of whether the radiation biology, which deals with carcinogenesis and some of

the other things which are involved in the standard nuclear medicine program are sufficient from the standpoint of therapy. I would say I doubt it.

And particularly as one moves into the area of the more current and new interest in the colloidal materials, particularly in cancer of the ovary, and treating and so forth.

Now I don't think we have used P-32 for treating effusions for years, because of nitrogen mustard and other spirosing agents are used.

But on the other hand, P-32 has become quite fashionable and I am amazed that your review didn't uncover this.

DR. BLAHD: I am not sure how to answer this question. It's a very profound question. Only to say that our programs involve a very extensive course of radiation biology, and I can speak from my own experience in my own program, we work very closely with the oncologists and also the radiation therapists in matters of this kind, as far as joint therapy is concerned. The residents in our programs have substantial experience in this area.

MR. CUNNINGHAM: Any other comments or questions from members?

Thank you very much.

Perhaps I will take a crack at summarizing where we seem to be from the Staff's standpoint. In order to accept board certification as evidence of training and experience to

qualify for NRC licensure, we will need two things:

First, the extent of the training, the number of hours of the training, and so forth. I think that's pretty clear.

The second thing we will need is some information which will allow the NRC, with the aid of its consultants, to establish the following ~~of training~~:

To somehow assess what individuals who are board-certified really know, and what the expected quality of their work is likely to be.

With that as a basis, I think we can proceed with evaluating various proposals for acceptance of board certification.

What I think we could do would be have the Staff review these with the assistance of the Advisory Committee. Where we have not satisfied this information, we would ask for more information.

I think as a matter of principle the Staff wants to accept, to the extent possible, board certification as evidence of appropriate qualifications for licensure. This obviously will save us and the licensees a fair amount of administrative time.

We will have to reexamine these various certifications in light of any rearrangement of our training requirements also. This is something that we will be working on over the coming

months.

Are there any comments from the committee?

Is there anything else we should be seeking on this?

Dr. Webster?

DR. WEBSTER: Well, I think you summarized it very well. I think, however, even if the contents of the three months' residency in nuclear medicine is spelled out in some detail, there is the overall question that in connection with other specialties, that hasn't been found adequate, and that one would have to document indeed the actual amount of training received. That is the state of the art right now.

Let us say not the Board of Radiology, but with the American Board of Radiology, the products of those three months' programs do not get an automatic issuance of a license. It obviously has to be taken into rather serious account.

MR. CUNNINGHAM: Any other comments?

DR. WALKER: I have one quick question I would like to bring up to the committee, and that is in these certifications by the American Board of Nuclear Medicine, how much emphasis should we place on the actual numbers of cases and whether or not each individual has actually worked with patients in these two groups, in IV and V?

MR. CUNNINGHAM: Dr. Workman?

DR. WORKMAN: We should have the numbers, I think, the numbers of cases, even though you have the certification on

the board, you shou still put down the number of cases. This would answer the problem about the intracavitary use of phosphates, for instance. You might have the American Board of Nuclear Medicine having never seen a chromic phosphate patient done. I don't think you should just be able to go out and do one of these until you have at least been in on three of them as is required.

MR. CUNNINGHAM: Any other comments? If not, we will move to the next agenda item. I think the Staff has some guidance on this one.

I want to bring up again the issue of treatment of cardiac dysfunction. Very briefly, you may recall that the FDA request about the use of iodine for cardiac dysfunction has lacked substantial evidence of the effectiveness. This use has been in existence for years. The basis for the lack of evidence is that no manufacturer has come forward with the information normally required in an IND to establish effectiveness, and the reason, as nearly as we can ascertain, that the industry hasn't stepped forward to do this is that there is very little demand for iodine for the treatment of cardiac dysfunction.

This has been reviewed when the issue came up whether or not the NRC should continue to permit its use in light of the FDA position on this matter. It was reviewed at least twice by the Medical Advisory Committee with everybody agreeing that its use was very small, but there are some

occasions for its possible use, and that the physician managing the patient should at least have the option of using this, if he chooses.

This position was brought up to our Commission again in a Staff paper, and they have asked the Staff to obtain from the Advisory Committee a formal recommendation about the use of iodine-131 for the treatment of cardiac dysfunction, and to include in that recommendation our basis for the recommendation.

Now in order to accomplish this objective, I believe that there are possibly three positions that we might take. The first is to delete the treatment from the licensing.

The second is to retain the treatment as it now stands, or to retain the treatment, but limit its use to some statement about limiting its use to appropriate cases.

Bill, do you want to expand on this before we try to reach some consensus of whether it should be in or out? And if it's in, the conditions under which it is in, and the basis for it.

DR. WALKER: Not really.

(Laughter.)

MR. CUNNINGHAM: Okay, you have answered my question.

DR. WALKER: I think it is pretty straightforward, as most of the committee members have already discussed this, and I think most of them have pretty set opinions on it.

MR. CUNNINGHAM: All right, then, I will call for

members of the committee to give an opinion, and this is one that we do need some opinion put forward on with regard to this.

Dr. Holman?

DR. HOLMAN: I preface my statement by certainly realizing that iodine-131 is a treatment for cardiac dysfunction disease is rarely used at the present time; but on the other hand, that the issue does raise certain questions of precedence. And in that regard I found Commissioner Kennedy's memorandum to be a highly succinct and to very effectively reflect my position on the matter, which is that in fact, as opposed to the FDA dropping a particular pharmaceutical from a specific application, in which case the pharmaceutical can still be applied by a physician at his discretion, if the benefit-risk ratio is sufficient to justify it, in the case where the NRC drops a particular radiopharmaceutical from a specific procedure, this is no longer the case. It is now illegal to use that radiopharmaceutical for an application unless the individual applies for an IND.

On that basis I feel quite strongly that the NRC should take a position of option No. 2, which would allow the physician the prerogative to use iodine-131 for cardiac dysfunction if the physician feels that this is the most effective treatment for that patient.

MR. CUNNINGHAM: Dr. Holman, you are basing your reason for keeping it up on the difference between the way NRC

and FDA laws would work?

DR. HOLMAN: Precisely.

MR. CUNNINGHAM: And that you feel that the physician should have the option of access to this treatment, if he chose it, without specifying the conditions under which he would use it?

DR. HOLMAN: Exactly.

MR. CUNNINGHAM: Do any other members of the committee want to make comments on this?

Dr. Webster?

DR. WEBSTER: Well, I'm not sure I'm really the person to speak to this, but I did read very carefully the three options which were placed before the committee, and Dr. Holman seems to have elected option 2.

On the other hand, option 3 would allow the same thing, but in a more cautious way, and my preference was option 3, which says to retain the use of iodine-131 for therapeutic treatment of cardiac dysfunction in group IV, but limit the treatment in cases in which it is the preferred method of therapy, and in the potential benefits to the patient far exceed the risk.

That's a little bit more enclosed, restricted than option 2, which is sort ofwide open. It says retain the use of iodine for therapeutic treatment, period.

I'd like to hear some further discussion on this.

MR. CUNNINGHAM: Dr. DeNardo?

DR. DE NARDO: Well, there is nothing wrong with

that statement, except I hope that it is true of everything we do, and I don't think -- you know, it seems somewhat icing on the cake to make that comment, in that the therapy you are giving has less risk than what you are giving it for.

It seems like a comment that should be present on everything, if we need to put it on.

Also I might just comment on No. 3, as well, in cases where nonradioactive drug therapy is not effective, I don't believe a suitable claim to impose upon the practice of medicine. There are some people who believe that nonradioactive drug therapy may be indeed more dangerous to many patients than radioactive iodine-131 therapy.

MR. CUNNINGHAM: Any other discussion on this point? If not, I will try to summarize the position of the committee to see if we have a consensus on it.

The first point is that use of iodine-131 for treatment of cardiac dysfunction has been in existence for a number of years.

The second point is that its use is very limited today, but nevertheless some physicians will want to use this in certain circumstances.

Number three, the committee feels that physicians should have the option of using this if they feel it is in the interest of the patient, for patient care.

Number four, under the FDA rules, particularly those rules under which they withdrew the drug as an effective drug,

a physician still has the option of using this in patient managemen without violation of FDA rules. If the NRC were to take a similar action, it would in fact remove the option of the physician to use this as he chose, because he would either have to have a special license amendment, which would be difficult to obtain for the patient he has to treat immediately; or he would have to file an IND for the FDA rules which, of course, we recognize again all this happens too late to treat the patient, when such a need is indicated.

I might add one point to this, that is that the committee in general believes that the use of iodine-131 for treatment of cardiac dysfunction is safe and that there may be instances where its use might indeed benefit the patient better than alternative uses.

That is where I'm coming out. Do we have some consensus from the committee on a statement like that, to go back to the Commission? Any discussion on this?

Capt. Briner.

CAPT. BRINER: I think there is one other thing that has not been addressed and that is the overall feeling, I think, in nuclear medicine that wherever possible, so long as safety is not impaired, there should not be any dichotomy in the regulations, in the Food & Drug Administration and those of the Nuclear Regulatory Commission.

That is to say, they should not be in opposition to

each other. In this case, where safety is not really an issue, that the issue exists, it may be an issue of effectiveness.

I could certainly support Dr. Holman's opinion, that when a physician decides that in a specific patient it would be beneficial, I think that right ought to exist for the physician, without the filing of an IND or an exemption.

MR. CUNNINGHAM: Any other comments? I see nods of agreement.

Dr. Goodrich?

DR. GOODRICH: I would just ask under alternative 2, what is the intent or what is the need for publishing this for public comment in the Federal Register?

MR. CUNNINGHAM: I don't know the exact status of the rulemaking, but -- do you know the answer to that, Bill?

DR. WALKER: I think this probably is because this probably infringes a little bit on the medical policy statement and therefore we would have to say that we are making an exception in this case.

MR. CUNNINGHAM: I think if you go back to our medical policy statement, a number of those things we have included in that statement was the fact that we were not going to examine on safety and efficacy, provided there was an effective IND from FDA. They don't have an NDA for this, so we are really going in the face of our policy statement. So we need to publish something, and that's why the Commission needs this

statement.

Are there any other comments on it? If not, we will use a statement something along the lines that I summarized as representing the consensus of this committee. and I see nods as I look up and down the line here.

If that is satisfactory, we will move on to the next subject.

T.6 The next subject that I want to cover, very briefly, is the work we are doing to amend our regulations to provide some relief in disposal of waste generated in medical and biomedical research.

By way of background on this, when waste disposal ground started to close down, there was a squeeze affecting mainly biomedical research on storage capacity, and there was some question whether or not this was leading to curtailment of research work.

In examining the problem, we find that ~~about~~ about 50 percent by volume of wastes generated in biomedical work that goes to burial grounds is either the scintillation fluids used in scintillation counting, mainly toluene, slightly contaminated with tritium, carbon-14, a few other things used to a lesser extent, and animal wastes, animal carcasses. Again, slightly contaminated with tritium or carbon-14, in the main.

We researched this some and have found that ~~the~~ the radioactivity in ~~the total~~ scintillation fluids ~~used~~ and in animals would amount

to about, I think, 23 curies of tritium per year, around the country, and about 6 curies of carbon-14, and all scintillation fluid and all animals, to give you some idea with respect to what we are talking about, 83 million scintillation vials per year.

Based on this, the Staff is in the process of trying to develop a regulation which will essentially release from control purposes, for purposes of radiation protection, scintillation fluids containing tritium or carbon-14, whose radioactivity content is less than .05 microcuries per gram.

The same would apply to the animal carcasses. This is not to say that they might not come under other federal, state and local laws for disposal of nonradioactive materials. Toluene is a carcinogen, a suspected carcinogen; at least some of the animals are pathogenic.

We are also considering raising the 1 curie cap in disposal to sewer systems to allow 5 curies of tritium and 1 curie of carbon-14, in addition to 1 curie of all other radioisotopes.

We have reviewed this proposal with a newly-formed task force on low-level radioactive waste disposal at the Federal Radiation Policy Council. That task force report that is now out supports the approach to eliminating these from control purposes, for purposes of radiation control.

We have been working with a group of consultants. Dr. Shahd has worked on this, as has Capt. Briner, and some others

to prepare our rule. We hope to go to the Commission with this rule in fairly short order.

Our proposed rule -- I think the members of the committee have an earlier version. It has some of the data and some dose estimates on there. We have picked as a worst case for calculating impacts that the materials would be incinerated as the most successful way to handle them, and we have calculated that for the largest type of facility, we could suspect something from a large medical institution like NIH, doses would be somewhere on the order of .01 millirems per year, and add that to food grown in the immediate vicinity if this material went into the ground, no more than 5 millirems per year.

But, really, it is boggling to try to apply the scenario that would really expose people to as much as that per year.

I would like to get some statement from the committee today, and any other group who represents a professional organization, on the utility of such a rule. Now in seeking such a statement, I would not ask you at this time to verify our numbers or commit yourself to the accuracy of our numbers as the quantity of radioisotopes involved here; nor do I ask you to make a commitment on the accuracy of our dose calculations.

But given that we are correct in the assessment of the quantities of radioactivity involved, and that our dose calculations are approximately right, I would like you to

address -- well, a couple of things, but let me add one more thing before we proceed here. We estimate that the dollar savings in not requiring scintillation vials as is presently done today for most of the animal carcasses, the dollar savings would be about $16 million. If one subtracts from that about $3 million to dispose of it in more conventional means of non-radioactive materials of the same chemical composition, there will be a dollar savings of about $13 million per year, realized largely in the area of biomedical research.

Now, with that as a background, I think last Saturday Dr. Rosalynn Yallow, I believe -- well, all members of the committee, and probably most people in this audience know Dr. Yallow is the 1977 Nobel Laureat in physiology and medicine -- has supported the written statement that supported the proposed rule for three main reasons, and I would like to read those reasons, because I believe that they are the important ones, and perhaps we can get some consensus from the committee on these things.

She stated the three reasons why she supported this are as follows:

Based on the calculations in the report and her own analysis, the risk to the public would be undetectable, since these had a negligible amount of radiation to the natural background.

The second point, the professional time lost in

accounting for and packaging of waste represents an enormous drain in the scientific community. This drain of talent is serious, particularly in view of the decreasing participation of the medical community in biomedical research.

And third, at this time, it is essential to preserve research resources -- when it is essential to preserve the research resources, tens of millions of dollars could be saved for useful investigative studies, rather than being dissipated because of regulations.

In other words, she is saying this $13 million a year, instead of going to disposing of waste, could be used for biomedical investigations which would result in much greater benefit to the public.

So on these three points, I would like some discussion from the committee. First with regard to the risk; secondly with the staff time lost of just packaging these materials, accounting for waste disposal; and third, the resources and funds dedicated to this.

Does any member of the committee wish to comment on this? Dr. Woodbury?

DR. WOODBURY: The information essential -- I just wondered why we hadn't done it years ago. We had to run into a crisis before action was taken. Certainly the documents and the figures that we have lend credence to the fact that the risks are minimal, and certainly at our institution, the time we have

spent on waste handling and waste management, in terms of manpower and manhours is a heavy expense.

The only caveat that I would raise is the question as to whether the individual handling of the waste material, if there would be the state surveillance or just what type of surveillance, just to make sure that there is no exposure, untoward exposure of people. To just give an example of one period in Michigan where there was a disposal site and some children were playing at the site, and that sort of thing. But this could still be handled through adequate surveillance of the method and means of disposal at the site.

So, number one, yes, I am all for the rule, per se, as long as there is some safeguards in terms of disposal at that individual site.

MR. CUNNINGHAM: Well, I fear we can't have it both ways. Either we say it is safe because of the nature of the radioisotopes and concentrations allowed and our analysis in which we try to pick the cases. We did look at land burials, landfill, that kind of thing. That would be included in the analysis, even though it isn't in the one that you have, but we can't do it both ways. We can't say it is safe, and by the same token, say, well, we're really not sure and we should monitor this. It's got to be rather clear one way or the other.

DR. WOODBURY: Under the circumstances, I have no questions on the rule as it now stands.

MR. CUNNINGHAM: Dr. Griem?

DR. GRIEM: Two comments:

The University of Illinois was one of the first to propose combustion of the scintillation fluid, the toluene, and the University of Illinois was burning it at Champaign-Urbana, to decrease the cost of their heating bill a little bit, and it seems that the state has not been upset about that.

The second comment I have is one would like to know through natural production of carbon-14 from cosmic radiation, how many curies are made, and maybe this 6 curies is 6 against 6 million over the top of the United States, and it probably is a pretty good figure as to how many curi of tritium -- not tritium, but carbon-14 are made by natural production.

MR. CUNNINGHAM: Well, the steady state environment is 200 million curies of carbon-14. That is steady state. So if you want to do the calculation on how much decays, you can figure out how much; tritium is 28 million in steady state. I think it's about four megacuries per year of tritium. I just don't remember.

Any other comments from the committee?

Dr. Webster?

DR. WEBSTER: I would simply like to congratulate you. I think this is a very intelligent thing to do, and an excellent solution to part of the waste problem for a lot of people. I think it is outstandingly successful from a cost-benefit point

of view. If you make the assumption that one rem of radiation might produce 100 fatal cases of cancer in a million people, and you applied those kind of numbers to the analysis that we have here, that is how many people are likely to be within 40 meters of the incineration point, for example, you can work out a kind of rough and ready number of a cancer case that you might produce if you were going to save $500 billion. That is a fantastically large advantage, costwise, versus the hazard.

MR. CUNNINGHAM: You see, Ted, I felt we had to do something like this after all the heat we got from you on ALARA.

(Laughter.)

DR. WEBSTER: Touché.

MR. CUNNINGHAM: Any member in the audience who would like to make a statement on this proposed rule? I see Dr. Smith from the Veterans Administration Hospitals

DR. SMITH: Jim Smith, Veterans Administration.

I think Rosalynn Yallow puts the thing most graphically when she says the ordinary organic garbage discharged from the Bronx Veterans Hospital every day contains more decaying K-40 than all of the discard from the various laboratories. We abhor this, Dick. It's another instance from my point of view, working with NRC, representing the VA, of the intelligent and cooperative action we get from you people. I would like to thank you for thinking of it.

MR. CUNNINGHAM: Well, thank you for that comment.

Any other comments, perhaps not so kind? Anybody else want to add anything on the utility of this rule?

If not, I think we have enough information to proceed. I think we have a feeling -- my sense of what the committee is saying on the various comments is that the rule is defendable and will be beneficial.

At this time there have been one or two more things that have come up that members of the committee wish to discuss and following which we will ask if there are any other agenda items, people from other organizations want to bring up.

I think one of the issues that came up that Dr. Griem mentioned, as well as some others, is the need for a guide on interpreting ~~[illegible]~~ administration the rule that has recently passed.

Dr. Griem, would you like to elaborate on your views on this, on whether or not we need some guidance?

DR. GRIEM: Informally a number of people have approached me and other members of the Advisory Committee concerning this administration rule that has been recently published in the Federal Register, and some of the people, particularly the therapeutic radiologists, have been concerned because there are a number of instances where the standards set forth would be very difficult to meet.

For instance, in the interstitial implantation of radioactive sources for permanent implant with a tolerance of

10 percent is quite difficult. There are other instances where the exact wording of what would be in a misadministration -- some patients are more sensitive than others, and the radiation oncologist, as he proceeds along a course of treatment, may modify the dose upwards or downwards, depending upon the clinical reaction so that his original specification of dose may be modified.

I think one can draw a similar situation where the cardiologist writes a particular dose of digitalis down, and then finds his patient doesn't tolerate digitalis at this level, or that something else is being administered that adversely affects the level of digitalis, and so we know a number of drugs now which modify the radiation effect.

So I think the whole question of misadministration, one needs a guide to the people going to look at how this rule should be enforced, and also a guide to the practicing radiation oncologist, so that he understands what the intent of this is. And I can go on and elaborate a number of instances where the intent was correct, and something happened that is really not controllable by the physician.

So that we are in an informal meeting suggesting a guide for the standards group and for the -- that this might be developed by the Advisory Committee, working with the Nuclear Regulatory Commission.

MR. CUNNINGHAM: Normally we would circulate a guide after the first one was drafted to the committee and, of

course, we would do that. We may want to be in touch with individual committee members to get the benefit of their thoughts prior to even starting to write this thing. I think that may be useful in some cases.

Do any other members of the committee want to comment on this subject?

How about other members of the staff? Do they have questions or comments? If not, I think that takes care of this subject.

Dr. DeNardo, you had a proposal, I thought, on how we should qualify statements about positions we entered in on the licensing. Perhaps you would like to elaborate on that, Both you and Dr. DeLand had the same thought originally.

DR. DE NARDO: Well, I'm not sure that I have a thought as to how to do it, other than the need on the actual license or a piece of paper that the person who has got the license from the NRC to use isotopes in the practice of medicine, and that is that there are many uses for that piece of paper, and if indeed we feel and you feel that this license is for radiation safety, the safety in the use, then that should be predominant in usually seen, obvious, or whatever you care to say, so that this piece of paper does say what we want it to say, and that it won't be misused or misrepresented as something showing competence.

I am not sure the best way to do it, other than that

I would hope that it would be on the top, on the front, and big enough to be very obvious.

MR. CUNNINGHAM: Dr. DeLand, did you want to add to that?

DR. DE LAND: This discussion started after the last NRC meeting, actually, and it's gone on in several other meetings. We were thinking in terms of the preamble or an official attachment to the licensure that stipulates that this license recognizes the educational background in the sciences and the competency to execute procedures with the safety of the patient and environment in mind; that this license in no way certifies as to the clinical diagnostic competency of the bearer, whoever it might be. Make it very clear. Because we know well that out in the community, particularly in hospitals, as you know, who have broad licenses, where you have a radiation safety committee that is usually relatively knowledgeable, but in a community, no hospital--once that license comes in, it is interpreted as a more or less carte blanche to do whatever it says on there.

And as we heard from the main discussion today, this can be erroneous.

MR. CUNNINGHAM: Thank you, Dr. DeLand.

What we will do is get together with our attorneys and try to work out an appropriate statement for a suitable place on the license, and circulate that to the committee for

their review and comment.

DR. DE LAND: Dick, I think this brings into perspective what the actual charge of this Commission is with respect to licensing physicians.

MR. CUNNINGHAM: It could well do that, yes.

That completes the list of agenda items that I have, on my list.

Bill, do you have any other items that you want to bring up at this time?

DR. WALKER: No.

MR. CUNNINGHAM: Do any other members of the NRC Staff have items that they would like to bring up?

Do any members of the committee have additional items that they want to bring forward at this time?

Dr. DeNardo?

DR. DE NARDO: I don't mean to be pushy, but I do find it important, and I was just going to ask whether we get our report from either the Federated Council or the Staff for next January's meeting in terms of the limited license position at that time?

MR. CUNNINGHAM: We are speaking of the licenses for limited practice, other than cardiology?

DR. DE NARDO: Right.

MR. CUNNINGHAM: I would hope that by the time we meet next January, it will either be December or January --

probably January -- that we will meet next, we will be able to take a position on this license. I can't promise anything at this point, because I don't know what kind of problem I'm going to run into in getting these various groups together. I just don't know.

I want to give these groups an opportunity to think about it. If, in fact, they are not interested in it, of course, we will proceed without them. But I do think they should be given an opportunity to do that.

The best I can promise you now is that we will get all of the Federated Council and various other groups that we think might have an interest, to see if they are willing to try to get together on the problem as did the cardiologists.

What the results will be, I can't tell you, but we will try to deal with that the next committee meeting, one way or the other. But we should give them an opportunity.

Do any other members of the committee have agenda items they want to bring up?

All right. If not, then, other members in the audience?

Dr. Smith.

DR. SMITH: In reflecting on what has been talked about today, I would like to start with one of the principles of the scholastic philosophist, that a person knows a thing in his own manner of knowing it, and I can know these things only

as a physician. So I am therefore very sympathetic and in agreemen with the views expressed by Dr. Woodbury, Dr. DeNardo, Dr. DeLand, Dr. Workman.

You know, whose life is it, anyway? It's the patient's life. I get an undercurrent in the discussions today of what will we permit the physician to do, not to say what we will permit the physician to get away with it. I don't think this is the point. I think an individual whose only excursion into nuclear medicine is to do some thyroid scans, which as Dr. DeNardo points out, will probably be unreadable, I really cannot take such a person seriously. And although he might dearly want to do these things, I really can't see him as a serious person in nuclear medicine.

We have had various analogies given today. If this is like that, I would like to remind you that analogies are not identities, and that these subjects must be considered in themselves.

From our point of view in the VA, if I could set up nuclear medicine services in the VA system in 172 hospitals, I would have, number one, the nuclear medicine person as the basic resource person in nuclear medicine. I would advise such a physician to have a good physicist working with him. But I think he should be the basic resource person.

And I would go even further in terms of architectural design. I would localize in one geographical area all use of

ionizing material to which people from various disciplines would be invited, endocrinologists, which I was years ago, gastro-enterologists, anybody who has a legitimate interest in pursuing his discipline in a competent way.

From my point of view, which is that of advising the VA what to do about nuclear medicine, all you can say is that it should be done by people who are competent to do it, and who can deliver the goods. They are available. They are not some-time people who show up now and then.

These are the thoughts that I would like to leave with the committee. Thank you for your attention.

MR. CUNNINGHAM: Thank you very much, Dr. Smith.

Do any other members of the public participants want to make a statement at this time?

If not, it is now 3:00 o'clock, and I think most of you or a great number of you have planes to catch. I will adjourn the meeting.

Thank you all for attending.

(Whereupon, at 3:00 p.m., the meeting was adjourned.)

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NUCLEAR REGULATORY COMMISSION

This is to certify that the attached proceedings before the

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in the matter of: Advisory Committee on The Medical Uses of Isotopes

Date of Proceeding: August 18, 1980

Docket Number: _____

Place of Proceeding: Bethesda, Maryland

were held as herein appears, and that this is the original transcript thereof for the file of the Commission.

Ann Riley

Official Reporter (Typed)

Ann Riley

Official Reporter (Signature)

CONSTITUTION
and
BYLAWS

1975

AMERICAN OSTEOPATHIC BOARD
OF NUCLEAR MEDICINE

AMERICAN OSTEOPATHIC BOARD OF NUCLEAR MEDICINE CONSTITUTION

ARTICLE I — NAME

The name of this organization shall be the AMERICAN OSTEOPATHIC BOARD OF NUCLEAR MEDICINE.

ARTICLE II — PURPOSES

Section 1. The purposes of the AMERICAN OSTEOPATHIC BOARD OF NUCLEAR MEDICINE shall be:

a) To define the qualifications required of osteopathic physicians seeking certification in the field (or fields) of nuclear medicine and of any other specialty or field of practice that may be assigned to this Board;

b) To evaluate the qualifications of those osteopathic physicians who may apply for certification in various disciplines of diagnostic and therapeutic nuclear medicine and of any other specialty or field of practice that may be assigned to it;

c) To conduct examinations in conformity with the Bylaws of this Board;

d) To recommend the issuing of certificates in the various disciplines of diagnostic and therapeutic nuclear medicine through the Advisory Board for Osteopathic Specialists and to the approval of the Board of Trustees of the American Osteopathic Association, to those osteopathic physicians who are found qualified;

e) To recommend revocation of certificates for cause after due and legal process;

f) To use every means possible to maintain a high standard of practice within the osteopathic profession.

ARTICLE III — PRACTICE OF NUCLEAR MEDICINE

For the purpose of the operation of the AMERICAN OSTEOPATHIC BOARD OF NUCLEAR MEDICINE, the following division of practice is defined: The practice of nuclear medicine shall consist of and include those fields of diagnostic therapeutic medicine which utilize radionuclides, excluding therapy with sealed sources.

ARTICLE IV — ORGANIZATION

Section 1. Membership

The AMERICAN OSTEOPATHIC BOARD OF NUCLEAR MEDICINE shall consist of six (6) members elected by the Board of Trustees of the American Osteopathic Association as provided for in the STANDARD BYLAWS OF CERTIFYING BOARDS.

Section 2. Officers

a) The officers of the AMERICAN OSTEOPATHIC BOARD OF NUCLEAR MEDICINE shall be a Chairman, Vice Chairman, and Secretary-Treasurer, whose powers and duties are as described in the STANDARD BYLAWS OF CERTIFYING BOARDS.

b) These officers shall be elected by this Board for a term of one (1) year at its annual meeting.

c) Officers shall continue to hold office until their successors are elected.

Section 3. Committees

a) There shall be two (2) standing committees of this Board and such other committees as may be from time to time authorized. The Chairman shall appoint all committees unless otherwise provided.

b) The Standing Committees shall be:

1. Credentials Committee
2. Examination Committee

Section 4. Advisory Board Representatives

a) There shall be a representative to the Advisory Board for Osteopathic Specialists appointed by and from the membership of this Board.

b) There shall be an alternate appointed by and from the membership of this Board empowered to act for the duly appointed representative in his absence.

Section 5. Meetings

The AMERICAN OSTEOPATHIC BOARD OF NUCLEAR MEDICINE shall hold an annual meeting and such other meetings as provided for by the Bylaws of the Board.

Section 6. Authority

The actions of the AMERICAN OSTEOPATHIC BOARD OF NUCLEAR MEDICINE are subject to the recommendations of the Advisory Board for Osteopathic Specialists and the approval of the Board of Trustees of the American Osteopathic Association.

ARTICLE V — AMENDMENTS

Subject to the review and recommendation of the Advisory Board for Osteopathic Specialists and the approval of the Board of Trustees of the American Osteopathic Association, this Constitution may be amended by a vote of two-thirds of the total membership of this Board at any meeting, provided each member has been notified at least fifteen (15) days prior to the date of the meeting and of the intention to amend.

AMERICAN OSTEOPATHIC BOARD OF NUCLEAR MEDICINE

BYLAWS

ARTICLE I — DUTIES

Section 1. This Board shall serve as an advisory body for all applicants for certification in the specialty or field of practice of Nuclear Medicine, and any other specialty or field of practice which may be assigned to its jurisdiction.

Section 2. This Board shall determine, in accordance with the provisions of these Bylaws, the appropriate standards of education, training and practice required for certification in the specialty or field of practice of Nuclear Medicine and of any other specialty field or practice which may be assigned to its jurisdiction, subject to the recommendation of the Advisory Board for Osteopathic Specialists and the approval of the Board of Trustees of the American Osteopathic Association.

Section 3. This Board shall establish detail rules for conducting all examinations, in accordance with the provisions of these Bylaws and shall provide for the conduct of examinations at least once a year, in accordance with its regulations and requirements.

Section 4. This Board shall file with the Advisory Board for Osteopathic Specialists, at the time specified by the Advisory Board, its recommendations concerning each applicant for certification, together with any pertinent information required by the Advisory Board for Osteopathic Specialists.

Section 5. This Board shall provide and recommend the issuing of certificates in all fields assigned to this Board in accordance with the provisions of these Bylaws.

Section 6. This Board shall recommend to the Advisory Board for Osteopathic Specialists and to the American Osteopathic Association Board of Trustees, the revocation of certificates in accordance with the provisions of these Bylaws.

Section 7. This Board shall provide permanent files for all records. It shall record and keep permanently on file all applications submitted to it and complete records of examination results and shall maintain a registry of diplomates. All examination papers and case reports required of applicants shall be kept on file for a period of five (5) years, after completion of the applicant's examination.

Section 8. This Board shall levy and collect from applicants the funds necessary to finance the operation of this Board as provided in the regulations and requirements.

Section 9. To arrange for all meetings necessary for this Board to carry out its functions as provided for in these Bylaws.

Section 10. This Board shall appoint two (2) members from the Board one of which shall function as a representative and the other as an alternate to the Advisory Board for Osteopathic Specialists. One of the two members may be the Secretary-Treasurer. In case of inability of the regular representative or alternate to attend the sessions of the Advisory Board for Osteopathic Specialists, the Chairman of this Board shall appoint alternates as provided in the Rules of Organization and Procedure of the Advisory Board for Osteopathic Specialists.

Section 11. This Board shall conduct its activities in relation to the officers of the American Osteopathic Association, the Advisory Board for Osteopathic Specialists, other Specialty Boards and applicants for certification as provided in the Rules of Procedure for Certifying Boards compiled by the Advisory Board for Osteopathic Specialists and approved by the Board of Trustees of the American Osteopathic Association.

Section 12. This Board shall make, in conformity to its Constitution and Bylaws, all necessary regulations and requirements to govern its activities which are not provided by the Advisory Board for Osteopathic Specialists and the Board of Trustees of the American Osteopathic Association.

Section 13. This Board shall report all actions, recommendations and activities through the Advisory Board for Osteopathic Specialists to the American Osteopathic Association Board of Trustees for approval.

ARTICLE II — MEMBERS

The AMERICAN OSTEOPATHIC BOARD OF NUCLEAR MEDICINE shall consist of six (6) members elected by the Board of Trustees of the American Osteopathic Association from nominees submitted by the American College of Osteopathic Internists, the American Osteopathic College of Pathologists, the American Osteopathic College of Radiology, the American Osteopathic Board of Internal Medicine, the American Osteopathic Board of Pathology, and the American Osteopathic Board of Radiology through the Board to the Advisory Board for Osteopathic Specialists and the Board of Trustees of the American Osteopathic Association.

Each member shall be a certified physician in good standing. (Insofar as practical, membership shall include a representative from each area within a given specialty or field of practice and a representative from each of the time divisions of the United States.)

Section 1. Election

The governing body or voting membership (as the case may be) of The American College of Osteopathic Internists, the American Osteopathic College of Pathologists, the American Osteopathic College of Radiology, the American Osteopathic Board of Internal Medicine, the American Osteopathic Board of Pathology, and the American Osteopathic Board of Radiology shall select one (1) candidate for each expiring term of prior appointed members on the AMERICAN OSTEOPATHIC BOARD OF NUCLEAR MEDICINE. The candidates selected shall be submitted through this Board to the Advisory Board for Osteopathic Specialists and to the Board of Trustees of the American Osteopathic Association.

Should a nominee submitted by the American College of Osteopathic Internists, the American Osteopathic College of Pathologists, the American Osteopathic College of Radiology, the American Osteopathic Board of Internal Medicine, the American Osteopathic Board of Pathology, and the American Osteopathic Board of Radiology fail to be approved by the Advisory Board for Osteopathic Specialists or the Board of Trustees of the American Osteopathic Association, then the respective college or board shall submit the name(s) of a different qualified individual(s). Said new nominee shall be submitted at the next meeting of the Advisory Board, which follows the date when the college or board was officially notified of the action by the Board of Trustees of the American Osteopathic Association.

In the event a new nominee(s) has not been submitted by the time and in the manner set forth above, then the Chairman of the Advisory Board for Osteopathic Specialists shall recommend to the Board of Trustees of the American Osteopathic Association a qualified candidate or candidates to fill the vacancy on this Board. The nominee's term shall be for the balance of the unexpired term.

SEE ENCLOSED REVISIONS

SEE REVISIONS ENCLOSED

Section 2. Term of Office

Members shall be elected for terms of three (3) years. The terms shall be staggered so that the new members elected in the year shall not constitute a majority of this Board.

The initial appointments shall be as follows:

One-year terms — representative from the American Osteopathic Board of Pathology and representative from the American Osteopathic Board of Radiology.

Two-year terms — representative from the American Osteopathic Board of Internal Medicine and representative from the American Osteopathic College of Pathologists.

Three-year terms — representative from the American College of Osteopathic Internists and representative from the American Osteopathic College of Radiology.

Members may be resubmitted for appointment.

Whenever a vacancy occurs on a certifying board due to the death or resignation of a board member whose term has not expired, the procedure outlined above shall be followed. If it is deemed urgent that the approval of the nominee be considered prior to the next regularly scheduled meeting of the AOA Board of Trustees, the Executive Director shall refer the matter to the Executive Committee of the AOA for their immediate action.

Members shall continue to serve until their successors are elected.

ARTICLE III — OFFICERS

The officers of the AMERICAN OSTEOPATHIC BOARD OF NUCLEAR MEDICINE shall be a Chairman, Vice Chairman and Secretary-Treasurer. The officers shall be elected by this Board during its annual meeting and shall serve for a term of one (1) year or until such time as their successors are elected.

Section 1. Duties of the Chairman shall be:

a) To preside at all meetings;

b) To appoint all committees;

c) To schedule meetings of this Board at such times and places as necessary to carry out the business of this Board;

d) To supervise all examinations;

e) To act as an exofficio member of all committees;

f) To sign all certificates issued by this Board.

Section 2. The duties of the Vice Chairman shall be:

a) To assume the duties of the Chairman when the latter is absent, or otherwise unable to fulfill them.

b) To assist the Chairman in the discharge of his duties.

Section 3. The duties of the Secretary-Treasurer shall be:

a) To keep a permanent file of records of all proceedings, transactions and rulings of this Board, and to keep on file all applications, examination papers and case records for a period of five (5) years.

b) To have printed and distributed all certificates, application forms, circulars of information, etc., authorized by this Board and necessary for the proper functioning of this Board.

c) To maintain in proper place and form the monies of this Board and to issue an accounting of that at annual meetings or at such times as requested by the Chairman of the Board.

d) To maintain a record of all diplomates in good standing and to supply upon request to governmental agencies, hospitals, physicians, schools and others entitled to such information a list of diplomates in good standing.

e) To have prepared in appropriate and complete form for presentation to the review committee of the Advisory Board of Osteopathic Specialists and support of the recommendation for certification of each candidate: the application, the examination records (written, oral and clinical), and other pertinent information requested.

f) To serve as the representative of this Board to the Advisory Board for Osteopathic Specialists, if so designated.

g) To sign all certificates issued by this Board as provided in Article VIII.

h) Prepare an annual report in keeping with the Rules of Procedure for Certifying Boards of the work done by this Board including a list of all applicants and results of their examinations and a resume of this Board's finances. This report is to be presented at the annual meeting of the Advisory Board for Osteopathic Specialists, and copies are to be supplied to the Chairman and Secretary of the Advisory Board and to the Executive Director of the American Osteopathic Association.

i) To cooperate with the Executive Director of the American Osteopathic Association in all matters pertaining to the annual registration of diplomates.

j) To notify the Executive Director of the American Osteopathic Association and Chairman and Secretary of the Advisory Board for Osteopathic Specialists of members and officers elected to this board and of appointments to the Advisory Board for Osteopathic Specialists.

ARTICLE IV — COMMITTEES

Committees shall be appointed by the Chairman, the duties of which shall be as herein prescribed:

Section 1. Credentials Committee

The Credentials Committee shall consist of three (3) members. Insofar as practical, the members shall represent different geographical districts.

The Credentials Committee shall:

a) Review all completed applications as submitted by the Secretary-Treasurer.

b) Conduct a comprehensive investigation of each applicant in accordance with the rules governing applications.

c) Prepare a complete report, with recommendations for each applicant, for presentation to the AMERICAN OSTEOPATHIC BOARD OF NUCLEAR MEDICINE at its next annual meeting.

Section 2. Examination Committee

The examination Committee shall consist of the Chairman of the Board and not less than two (2) members of the Board. The Chairman of the Board may be the Chairman of the Examination Committee.

a) Plan and prepare for the conduct of examinations in the fields of practice under the jurisdiction of this Board in accordance with the rules stated in these Bylaws and Regulations and Requirements of this Board.

b) Report the results of the examinations to this Board.

ARTICLE V

ADVISORY BOARD REPRESENTATIVES

a) The Advisory Board representative shall be appointed annually from and by the membership of the Certifying Board to represent the AMERICAN OSTEOPATHIC BOARD OF NUCLEAR MEDICINE on the Advisory Board for Osteopathic Specialists, and in all matters where such representation is required.

b) The alternate representative to the Advisory Board shall be appointed annually from and by the membership of the Certifying Board. He shall be empowered to act for the duly appoin. d representative in his absence.

c) The Advisory Board representative shall:

i) Transmit from the Certifying Board all information certifying to the adequacy of the examination.

ii) Have available files and records of all candidates being recommended for certification and such other files as may be requested in advance.

iii) Report to the Advisory Board on the adequacy of the examinations and the recommendation of the Certifying Board on applicants who have completed the examinations.

iv) Report to the Certifying Board regarding actions and proceedings of the Advisory Board.

ARTICLE VI — MEETINGS

Section 1. The annual meeting of the AMERICAN OSTEOPATHIC BOARD OF NUCLEAR MEDICINE shall be held at such time and place as is determined by the majority action of the Board. However, this meeting, which has for one of its purposes examination of candidates for certification shall be in proper time sequence with meetings of the Advisory Board and American Osteopathic Board of Trustees to insure proper continuity of applicant evaluation and disposition. Proper and due notice of the annual meeting shall be forwarded to each member of the Board not later than sixty (60) days prior to the meeting.

Section 2. Special meetings of the Board which are deemed necessary for transaction of business may be called by the Chairman or by written request of no less than three (3) members of the Board, notice of which meeting shall be received not less than fifteen (15) days prior to the date of the meeting. The time and place of the special meeting shall be at the discretion of the Chairman.

Section 3. Quorum

For the transaction of business at any meeting of the Board, four (4) members shall constitute a quorum.

Section 4. Governing Rules

The meeting of the AMERICAN OSTEOPATHIC BOARD OF NUCLEAR MEDICINE shall be governed by **Roberts' Rule of Order Newly Revised** unless otherwise specified in these Bylaws.

ARTICLE VII

REQUIREMENTS FOR CERTIFICATION

Section 1.

To be eligible to receive certification from the AMERICAN OSTEOPATHIC BOARD OF NUCLEAR MEDICINE, the applicant must meet the following minimum requirements:

a) He must be a graduate of an approved osteopathic college.

b) He must be licensed to practice in the state or territory where he conducts his practice.

c) He must be able to show evidence of conformity to the standards set in the Code of Ethics of the American Osteopathic Association.

d) He must have been a member in good standing of the American Osteopathic Association or the Canadian Osteopathic Association, and the divisional society of the American Osteopathic Association of the state or province in which he practices for a continuous period of at least two (2) years immediately prior to the date of certification. Divisional society requirement is not applicable to those on active duty in the uniformed service or those employed full time by the Veterans Administration.

e) He must have satisfactorily completed an internship of at least one (1) year in a hospital approved for intern training by the American Osteopathic Association. Certifying Boards may accept a minimum of five (5) years in general practice in lieu of one (1) year of internship for those who graduated in 1946 and prior thereto.

f) Requirements for admission to examination. Candidates who have completed by June 30, 1974, one of the following combinations of training and experience will be considered for admission to the examination.

i) An AOA-approved internship and ten (10) years experience in Nuclear Medicine;

ii) An AOA-approved internship, one (1) year AOA-approved residency training in Internal Medicine, Pathology, or Radiology and five (5) years experience in Nuclear Medicine;

iii) Certification by the American Osteopathic Board of Internal Medicine, the American Osteopathic Board of Pathology, or the American Osteopathic Board of Radiology and one (1) year AOA-approved training in Nuclear Medicine, or (3) years experience in Nuclear Medicine;

iv) An AOA-approved internship plus one (1) year of AOA-approved residency training and two (2) years training in Nuclear Medicine;

v) Certification obtained from the American Board of Nuclear Medicine up until June 30, 1975, will be accepted in lieu of examination by the American Osteopathic Board of Nuclear Medicine; with the exception of the above-named certification, no certification in Nuclear Medicine will be issued without examination;

vi) Other combinations of training and experience may be approved on an individual basis after review by the Board, and with the approval of the AOA.

REVISED SEE ATTACHED

g) Following satisfactory compliance with the prescribed requirements for examination, the applicant shall be required to pass appropriate examinations planned to evaluate his understanding of the scientific bases of the problems involved in his specialty or field of practice, his familiarity with the current advances in the specialty or field of practice, the possession of sound judgment and of a high degree of skill in the diagnostic and therapeutic procedures involved in the practice of the specialty or field of practice.

Oral, written and clinical examinations shall be conducted and required in the case of each applicant. ~~The practical or clinical examinations shall be conducted only after the required years of practice have been completed. Two members of this Board shall personnally review, if not perform, the grading of each written examination. The conduct of the clinical examination may be delegated to a committee of not fewer than two (2) individuals naturally qualified in the specialty or field of practice. A full description of the method of conducting the examination shall be formulated in this Board's Regulations and Requirements, and provision for re-examination shall be made~~.

Applicants desiring examination for certification shall be required to file an application which shall set forth the applicant's qualifications for examination as stated in paragraphs a-f in Section 1. The procedure for filing applications shall be set forth in the Regulations and Requirements.

Section 2.

Subject to the recommendation of the Advisory Board for Osteopathic Specialists and the approval of the Board of Trustees of the American Osteopathic Association, the AMERICAN OSTEOPATHIC BOARD OF NUCLEAR MEDICINE may require such further training in each of the fields coming under the jurisdiction as in its judgment such field may require, provided that the additional requirements for each field are clearly set forth in the Regulations and Requirements of this Board. Additions to requirements shall not go into effect until one (1) year subsequent to the announcement of such change.

INSERT NEW ARTICLE VIII SEE ATTACHED

ARTICLE ~~VII~~ VIII — CERTIFICATES

Section 1. Issuance

Certificates shall be issued by the AMERICAN OSTEOPATHIC BOARD OF NUCLEAR MEDICINE to applicants who have conformed to all requirements for certification described in Article VII of these Bylaws, and who have received the recommendation of the Advisory Board for Osteopathic Specialists and the approval of the Board of Trustees of the American Osteopathic Association.

Each such certificate shall be signed by the Chairman and the Secretary-Treasurer of this Board. No certificate is valid until it has been signed by the Executive Director of the American Osteopathic Association.

Section 2. Revocation and Reinstatement

Immediately following official notification that a diplomate no longer meets any one of the following requirements for maintaining certification status with the American Osteopathic Association, such certificate shall be auto-

matically revoked and removed from the Certification Register of the AOA:

a) Nonpayment of dues of the AOA or the Canadian Osteopathic Association;

b) Nonpayment of annual certification registration fee;

c) Nonmember of divisional society of the AOA (if such exists) in the state or province in which the diplomate practices.

The Certifying Board shall have the power to recommend to the Advisory Board for Osteopathic Specialists and the Board of Trustees of the American Osteopathic Association the revocation of the certificate of any diplomate whose certificate was obtained by fraud or misrepresentation, who advertises, exploits his certificate, violates the Code of Ethics of the American Osteopathic Association or otherwise disqualifies himself.

Reinstatement of a certificate that has been revoked must first be approved by the Certifying Board, the Advisory Board for Osteopathic Specialists and the AOA Board of Trustees.

Section 3. Reinstatement of Certification for Holders of m.d. Degree from the California College of Medicine.

The procedures for reinstatement of certification for holders of the m.d. degree from the California College of Medicine shall be as follows:

a) Reapply for AOA membership in accordance with established policy and apply for divisional society membership in the state in which he intends to practice.

b) Show continuous membership in the AOA and divisional society for at least two (2) years immediately prior to the date of certification;

c) Apply to Certifying Board for procedures to determine whether recertification can be considered;

d) Shall submit evidence of professional activities, practice and education from the time of separation from the AOA to the time application is made for AOA and divisional society membership;

e) Shall take an examination given by the Certifying Board to determine professional competence. This examination shall be conducted at the time of regular examinations for certification by each Certifying Board, and the expense of the examination shall be borne by the applicant.

f) The former D.O. diplomate shall be advised of the results of the examination and, where indicated, advised by the Certifying Board of the areas of deficiency.

g) A Certifying Board may conduct a further examination before recommending an applicant for certification.

h) Methodology for all examinations for this special category shall be submitted by each Certifying Board to the Advisory Board for Osteopathic Specialists for approval.

Section 4. Annual Registration

To remain in good standing the diplomate shall pay an annual certification registration fee to the AOA Executive Director as provided in the RULES OF PROCEDURE FOR CERTIFYING BOARDS.

ARTICLE X — AMENDMENT

Subject to the review and recommendation of the Advisory Board for Osteopathic Specialists and the approval of the Board of Trustees of the American Osteopathic Association, these Bylaws may be amended by a two-thirds vote of the total membership of this Board at any meeting provided each member has been notified at least thirty (30) days prior to the date of the meeting, of its being called and of the intention to amend.

AMERICAN OSTEOPATHIC BOARD OF NUCLEAR MEDICINE REGULATIONS AND REQUIREMENTS

To expedite and direct the activities of the American Osteopathic Board of Nuclear Medicine and its conduct of the certification program, the following regulations and requirements are hereby placed in effect.

MEETINGS

Stated Meetings

The American Osteopathic Board of Nuclear Medicine shall hold a regular annual meeting to transact business at such time and place as the Board may decide.

Special Meetings

Special or called meetings may be held at a time and place as the Board may decide. Notices of the meeting shall be mailed to each member not less than fifteen (15) days prior to the proposed meeting date. Meetings may be called by the Chairman or by written request of no less than three (3) members of the Board.

ORDER OF BUSINESS

The Chairman shall prepare an agenda to be distributed to all members before each regular meeting.

The order of business of the annual meeting shall be:

1. Call to order
2. Roll Call
3. Report of the Secretary-Treasurer
4. Communications
5. Report of Credentials Committee
6. Report of Examining Committee
7. Reports of Special Committees
8. Old Business
9. New Business
10. Adjournment

DISPOSITION OF FUNDS

a. A legally recognized bank is the repository of all funds of this Board. It may be chosen for the convenience of the Secretary-Treasurer.

b. The checks may be signed by the Secretary-Treasurer or the Chairman of the Board.

c. An annual audit is required. The presentation of the invoices shall become an integral part of the record of the Secretary-Treasurer.

d. A bond for the Secretary-Treasurer is required when the funds accumulate to the sum of $1,000.00 or more.

COMMITTEES

A. Credentials Committee

The Credentials Committee shall:

1) Review all completed applications as submitted by the Secretary-Treasurer.

2) Conduct a comprehensive investigation of each applicant in accordance with the rules governing applications.

3) Prepare a complete report, with recommendations for each applicant, for presentation to the American Osteopathic Board of Nuclear Medicine at its next annual meeting.

B. Examination Committee

The Examination Committee shall:

1) During the course of the fiscal year between annual meetings collect, secure, identify, tabulate and otherwise arrange all materials which the Committee will require to give a proper examination of the candidates.

2) During the course of the fiscal year between annual meetings prepare an examination in nuclear medicine following the basic concepts described as follows:

a) The examination shall be in two (2) parts.

1. The Practical examination shall include but not be limited to:
   - A. Interpretation of scans.
   - B. Evaluation of clinical, nuclear medicine, and laboratory data for the purpose of rendering diagnoses.
2. The Academic examination shall include but not be limited to:
   - A. Oral examination by the examining Committee on the subject material of the examination being taken.
   - B. Written examination as prepared by the examination Committee or other agency as determined by the American Osteopathic Board of Nuclear Medicine.

3) The scope, length and breadth of each examination shall be at the discretion of the Examining Committee and Board, within the limits established by the Advisory Board for Osteopathic Specialists. Each examination shall be of sufficient breadth and comprehensiveness to adequately evaluate each candidate so as to qualify him (her) as a specialist in Nuclear Medicine.

4) Examinations shall be proctored by the Secretary-Treasurer of the American Osteopathic Board of Nuclear Medicine or his designee. The examination shall be given at a time and place as designated by the American Osteopathic Board of Nuclear Medicine.

5) The Examination Committee shall provide the examination questions and answers and complete information about the time and place of the examination to the Secretary of this Board.

6) The Examination Committee shall use an assigned number for each applicant, designated by the Secretary-Treasurer of this Board. This identifying number will be used in lieu of the applicants name. The applicant's name will not appear anywhere in the examination book, answer sheets, and/or score sheets, except on indiviual score sheets provided for the oral examination.

7) The examination in Nuclear Medicine shall be graded as follows:

A) The average grade of the practical examination shall constitute 50% of the final grade. The average of the combined oral and written examinations shall constitute 50% of the final grade. The average of these two (2) grades shall be the final grade and must be 75% or greater.

B) There shall be a single final grade. The maximum score that can be achieved is 100%. A score of less than 75% (raw score) shall be considered failure and the candidate may not be recommended for certification.

C) The final grade shall be determined by the American Osteopathic Board of Nuclear Medicine in keeping with the policies and directives of the Advisory Board of Osteopathic Specialists.

D) A record of each examination must be signed and dated by the examiner upon issuing the grade of the examination, but in no instance is the individual examiner's record to be placed upon the examination book or papers, except for the oral score sheet.

E) At least three (3) examiner's grades must be utilized to compute the final grade average.

ADVISORY BOARD REPRESENTATIVE

1) The representative to the Advisory Board for Osteopathic Specialists shall be appointed from and by the membership of this Board.

2) The alternate shall be appointed from and by the membership of this Board. The alternate shall be empowered to act for the duly appointed representative in his absence.

3) The representative shall fulfill this duty of representing the American Osteopathic Board of Nuclear Medicine in all matters where such representation is required.

ELECTION OF MEMBERS

The American Osteopathic Board of Nuclear Medicine shall consist of six (6) members, one submitted from the American Osteopathic Board of Internal Medicine, the American Osteopathic Board of Pathology, the American Osteopathic Board of Radiology, the American College of Osteopathic Internists, the American Osteopathic College of Pathologists, and the American Osteopathic College of Radiology through this Board to the Advisory Board for Osteopathic Specialists and to the Board of Trustees of the American Osteopathic Association for approval. Insofar as possible, there shall be a representative from each geographical time division of the United States on this Board.

REVISION SAME AS PAGE 4

Members shall be elected for terms of three (3) years. The terms shall be staggered so that the new members elected in any year shall not constitute a majority of this Board.

The initial appointments shall be as follows:

One-year terms — representative from the American Osteopathic Board of Pathology and,
representative from the American Osteopathic Board of Radiology.

Two-year terms — representative from the American Osteopathic Board of Internal Medicine and,
representative from the American Osteopathic College of Pathologists.

Three-year terms — representative from the American College of Osteopathic Internists and,
representative from the American Osteopathic College of Radiology.

Members may be resubmitted for appointment. Members shall continue to serve until their successors are elected.

OFFICERS

The officers of the American Osteopathic Board of Nuclear Medicine shall be:

Chairman, Vice Chairman, and Secretary-Treasurer.

The Officers shall be elected by this Board for a term of one (1) year at its annual meeting.

Officers shall serve until their successors are elected.

DEFINITION

The practice of Nuclear Medicine is defined as consisting of and including those fields of diagnostic therapeutic medicine which utilize radionuclides but excluding therapy with sealed sources.

APPLICATIONS FOR EXAMINATION

The applications obtained from the office of the Secretary-Treasurer of this Board shall be signed by the applicant and filed with the Secretary-Treasurer of this Board ~~prior to April 1st of the year in which the applicant intends to appear for examination~~.
30 days prior to that years examination.

REQUIREMENTS FOR CERTIFICATION

To be eligible to receive certification from the American Osteopathic Board of Nuclear Medicine, the applicant must meet the following requirements:

1) He must be a graduate of an approved osteopathic college.

2) He must be licensed to practice in the state or territory where he conducts his practice.

3) He must be able to show evidence of conformity to the standards set in the Code of Ethics of the American Osteopathic Association.

4) He must have been a member in good standing of the American Osteopathic Association or the Canadian Osteopathic Association, and the divisional society of the American Osteopathic Association of the state or province in which he practices for a continuous period of at least two (2) years immediately prior to the date of certification. Divisional society requirement is not applicable to those on active duty in the uniformed services or those employed full time by the Veterans Administration.

5) He must have satisfactorily completed an internship of at least one (1) year in a hospital approved for intern training by the American Osteopathic Association. Certifying boards may accept a minimum of five (5) years in general practice in lieu of one (1) year of internship for those who graduated in 1946 and prior thereto.

6) Requirements for admission to examination: Candidates who have completed by June 30, 1974, one of the following combinations of training and experience will be considered for admission to the examination.

a) An AOA-approved internship and ten (10) years' experience in Nuclear Medicine;

b) An AOA-approved internship, one (1) year AOA-approved residency training in Internal Medicine, Pathology, or Radiology and five (5) years experience in Nuclear Medicine;

c) Certification by the American Osteopathic Board of Internal Medicine, the American Osteopathic Board of Pathology, or the American Osteopathic Board of Radiology and one (1) year AOA-approved training in Nuclear Medicine or three (3) years experience in Nuclear Medicine;

d) An AOA-approved internship plus one (1) year of AOA-approved residency training and two (2) years training in Nuclear Medicine.

e) Certification obtained from the American Board of Nuclear Medicine up until June 30, 1975, will be accepted in lieu of examination by the American Osteopathic Board of Nuclear Medicine; with the exception of the above-named certification, no certification in Nuclear Medicine will be issued without examination;

f) Other combinations of training and experience may be approved on an individual basis after review by the Board, and the approval of the American Osteopathic Association.

7) He must submit a copy of his AEC license or copy of agreement license from his state.

8) He must submit a preceptor statement if one is available.

9) He must have letters of recommendation from two (2) certified osteopathic physicians in his specialty field.

10) He must submit proof of his internship, residency, and any other training.

REVISED SEE ATTACHED

FEES

A) The application fee for Board eligibility, as determined by the American Osteopathic Board of Nuclear Medicine, shall be $50.00, and is not refundable.

B) An additional fee of $250.00 is required before the examination is given, payable immediately upon notification of acceptance of the application. This constitutes the examination fee and is not refundable to the applicant.

C) Re-examination will require a fee of $250.00 for each re-examination.

EXAMINATIONS

A) The applicant will be notified by the Secretary-Treasurer of the Board as to the time and place of the examination. He will be assigned a number to be used in place of his name on the examination book and answer sheets.

B) Examinations for certification are given annually at the time and place designated by the American Osteopathic Board of Nuclear Medicine.

C) Nature of the examination: Written examination shall consist of a set of written questions with the rules governing examination questions and procedures as follows:

1. The examination will be so designed, conducted and constructed so as to be comprehensive covering the field of Nuclear Medicine.
2. Practical examination will include both scan interpretation, correlation of laboratory nuclear medicine data and basic nuclear physics.
3. Oral examination shall be conducted by at least four (4) members of the Board and shall be so conducted as to assist in determining the candidate's qualifications as a specialist in Nuclear Medicine.

D) Failure to achieve a final passing grade (75%) in any of the above categories, i.e., oral, written or practical, shall require the applicant to be re-examined in all categories, regardless of the scoring on any individual part.

E) Re-Examinations:

1. Re-examination may not be taken at any other time than that of the regular annual examination.
2. Re-examination may not be taken within a period of less than one (1) year from the preceding examination.
3. A candidate may be re-examined two (2) additional times. If he should be unsuccessful after a total of three (3) attempts, he must show evidence of further study and/or training acceptable to the American Osteopathic Board of Nuclear Medicine.

NOTIFICATION TO APPLICANT

Following the annual meeting of this Board, the Secretary-Treasurer shall notify each applicant of the results in his particular case, informing him the action of this Board is subject to the approval of the Advisory Board for Osteopathic Specialists and the Board of Trustees of the Osteopathic Board of Nuclear Medicine.

ISSUANCE OF CERTIFICATES

1) The Secretary-Treasurer of the American Osteopathic Board of Nuclear Medicine, upon receipt of notification from the Executive Director of the American Osteopathic Association that recommendation for certification of an applicant has been approved by the Board of Trustees of the American Osteopathic Association shall within sixty (60) days have the certificate prepared, shall number and have it signed by the Chairman and the Secretary-Treasurer of this Board and record it in his register, and he shall then forward it to the Executive Director together with a letter which clearly indicates to whom the certificate shall next be sent.

2) The Executive Director of the American Osteopathic Association shall sign and register the certificate and shall then forward it to the Secretary-Treasurer of the American Osteopathic Board of Nuclear Medicine and shall notify the Secretary of the Advisory Board for Osteopathic Specialists of the issuance of the certificate to allow completion of the Advisory Board's record of this Board's action.

3) The Secretary-Treasurer of the American Osteopathic Board of Nuclear Medicine shall then forward the certificate to the diplomate, together with an appropriate letter of transmittal.

4) A "receipt" (obtained from the Secretary of the Advisory Board for Osteopathic Specialists) must be filled out in duplicate by the Secretary-Treasurer of the American Osteopathic Board of Nuclear Medicine and transmitted with the certificate to the diplomate with instructions to sign both copies of the "receipt" and return the original to the Secretary-Treasurer of this Board.

REVOCATION OF CERTIFICATE

To remain in good standing, a diplomate must continue to be a member in good standing of the American Osteopathic Association and of his divisional society. Divisional society requirement is not applicable to those on active duty in the uniformed services or those employed full time by the Veterans Administration.

A certificate holder shall pay an annual registration fee of $15.00. Notice of annual registration will be mailed with the annual dues notice of the American Osteopathic Association.

AMENDMENTS

These REGULATIONS AND REQUIREMENTS may be amended at any stated or called meeting by a majority vote of the membership of the American Osteopathic Board of Nuclear Medicine subject to the approval of the Advisory Board for Osteopathic Specialists and the Board of Trustees of the American Osteopathic Association.

NOTES

AOBNM

P.L Vaca

American Osteopathic Board of Nuclear Medicine

August 7, 1980

Richard Cunningham, Ph.D., Chairman
Advisory Committee on Medical Uses of Isotopes
Division of Fuel Cycle & Materials Safety
Nuclear Regulatory Commission
Washington, D.C. 20555

Dear Dr. Cunningham:

This letter will serve to confirm our recent telephone conversation regarding the desire for recognition of certification by the American Osteopathic Board of Nuclear Medicine by the Nuclear Regulatory Commission for appropriate categories of nuclear material.

The American Osteopathic Board of Nuclear Medicine examines candidates in the discipline of nuclear medicine by means of written, oral and scan interpretation examinations. Subsequent to satisfactory completion of the three-part examination the Board of Nuclear Medicine recommends to the Advisory Board of Osteopathic Specialists the names of those candidates who have successfully completed the requirements for certification for their recommendation to the Board of Directors of the American Osteopathic Association.

The American Osteopathic Board of Nuclear Medicine is a conjoint board representing the disciplines of internal medicine, radiology and pathology. Representation on the board is made through appointments by the American Osteopathic College of Nuclear Medicine and consists of two members certified in internal medicine, radiology and pathology respectively, as well as certification by the American Osteopathic Board of Nuclear Medicine. All members of the board are certified in Nuclear Medicine by means of examination.

5200 S. Ellis Ave. / Chicago, Illinois 60615 / (312) 947-4951

Eligibility requirements to sit for the examinations given by the American Osteopathic Board of Nuclear Medicine are listed in the accompanying copy of the Constitution and By-laws of the AOBNM.

If there is any additional information which you may require to assist our organization in achieving recognition by the Nuclear Regulatory Commission, please let me know. I understand the minutes of your meeting will be held open for an additional thirty days after the August 18th. meeting.

I hope to have a representative ofour organization present for your meeting.

Sincerely,

G. T. Caleel, D. O.

G. T. Caleel, D. O.
Chairman

GTC/cmt

AMERICAN OSTEOPATHIC BOARD OF NUCLEAR MEDICINE

AMENDMENTS TO THE CONSTITUTION, BY-LAWS AND RULES AND REGULATIONS AS APPROVED BY THE ADVISORY BOARD FOR OSTEOPATHIC SPECIALISTS AND THE BOARD OF TRUSTEES OF THE AMERICAN OSTEOPATHIC ASSOCIATION.

PAGE 4, ARTICLE II - MEMBERS

The American Osteopathic Board of Nuclear Medicine Shall consist of six (6) members elected by the Board of Trustees of The American Osteopathic Association from nominees submitted by the American Osteopathic College of Nuclear Medicine through this Board to the Advisory Board for Osteopathic Specialists and the Board of Trustees of the American Osteopathic Association.

Each member shall be a physician in good standing, certified by the American Osteopathic Board of Nuclear Medicine. Insofar as practical, membership shall include a representative from each area within a given specialty or field of practice and a representative from each of the time divisions of the United States.

Section 1. Election

The governing body or voting membership of the American Osteopathic College of Nuclear Medicine shall nominate one (1) candidate for each expiring term. These candidates shall be nominated so as to maintain the balance of two certified internists, two certified pathologists and two certified radiologists on the American Osteopathic Board of Nuclear Medicine. The candidates nominated shall be submitted through this Board to the Advisory Board for Osteopathic Specialists and to the Board of Trustees of the American Osteopathic Association.

Should a nominee submitted by the American Osteopathic College of Nuclear Medicine fail to be approved by the Advisory Board for Osteopathic Specialists or the Board of Trustees of the American Osteopathic Association, the College shall submit the name (s) of a different qualified individual(s). Said new nominee shall be submitted at the next meeting of the Advisory Board, which follows the date when the College was officially notified of the action by the Board of Trustees of the American Osteopathic Association.

Section 2. Term of Office

A. The term of office as a member of the American Osteopathic Board of Nuclear Medicine is for three (3) years.

B. Incumbent members of the American Osteopathic Board of Nuclear Medicine shall serve until their sucessors are elected and seated.

C. Whenever a vacancy occurs on the certifying board due to death or resignation of a board member whose term of office has not expired, nominations shall be submitted from Diplomates in good standing by the American Osteopathic College of Nuclear Medicine. If it is deemed urgent that the approval of the nominee be considered prior to the next regularly scheduled meeting of the AOA Board of Trustees, the Executive Director shall refer the matter to the Executive Committee of the AOA for their immediate action.

D. Members shall continue to serve until their successors are elected.

Page 9 Board Eligibility Continued----------

7. A candidate may lose "Board Eligibility" status by:

A) Failure to take the certifying examination within the period of "Board Eligibility".

B) Failure to successfully complete the examination within the period of "Board Eligibility".

8. Each certifying Board shall, upon termination of "Board Eligibility" status, notify the candidate in writing. The notice must include the reason or reasons for loss of status. Copies of each notice shall be filed with the secretary of the Advisory Board for Osteopathic Specialists and the AOA Office of Education. The candidate receiving such notice has the right to appeal to the Advisory Board for Osteopathic Specialists.

Section 2. Re-entry To Certification Process

1. A candidate who has lost "Board Eligibility" and who wishes to re-enter the certification process may submit, by individual petition, a request for such re-entry. The petition must be made to the appropriate certifying board. If such petition is approved by the appropriate certifying board, the individual shall not be identified as "Board Eligible".

2. Each certifying board must provide such candidate with a written list of deficiencies and, further, cooperate with the evaluating committee of the appropriate specialty college or academy in developing a training program designed to the individual's needs.

3. Upon documented completion of the approved program, the candidate may take the certifying examination.

Page 14, Election of Members - This Will Be The Same As Page 4, Article II.

Page 15, Requirements For Certification - This Will Be The Same As Page 8, Article VII With The Following Exception Which Occurs On Page 16:

7) He must submit evidence of his participation on a NRC and/or state license for the human use of radioisotopes as it may appear.

8) He must have letters of recommendation from two (2) osteopathic physicians certified in Nuclear Medicine

9) He must submit proof of his internship, residency, and any other training.

Page 16, Fees

B) An additional fee as determined by the Board is required before the examination is given, payable immediately upon notification of acceptance of the application. This constitutes the examination fee and is not refundable to the applicant.

C) Re-examination will require as determined by the Board for each re-examination.

Medical Center

50 Irving Street, NW.
Washington, D.C. 20422

Veterans Administration

1729

August 7, 1980

Mr. Richard Cunningham, Director
Division of Fuel Cycle and Material Safety
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Dear Mr. Cunningham:

I would like to sumbit my objections to your agency's training criteria for physicians whose use of byproduct material is limited to nuclear cardiology. The possibility that a physician could be directing a nuclear cardiology laboratory with only 250 hours of clinical experience is totally unjustified. This amount of time could never be sufficient to instruct someone in the proper use of radiopharmaceuticals.

The likely result of allowing this regulation to stand would be to divide and ultimately destroy the speciality of Nuclear Medicine and allow incompletely trained individuals to use potentially hazardous materials. The public welfare would not be served.

I feel that a minimum of one year training with instruction in all aspects of nuclear procedures should be an absolute minimum requirement. I hope in the light of reason you will agree.

Sincerely yours,

H. Richard Bates, M.D.
Assistant Chief, Nuclear Medicine

In Reply Refer To:

UNIVERSITY HOSPITAL

July 28, 1980

Mr. Joseph Del Medico
U.S. Nuclear Regulatory Commission
Office of Nuclear Material Safety and Safeguards
7915 Eastern Avenue
Silver Springs, MD 20910

Dear Mr. Del Medico:

Enclosed is a copy of my letter dated June 30, 1980 to Joseph F. Ross, M.D. secretary of The American Board of Nuclear Medicine stressing why therapy with internally administered radionuclides should be retained in the training program and in the Board requirements of the American Board of Nuclear Medicine.

Also enclosed is a letter to Joe Ross dated 7/28/80 presenting new data that further corroborates the message in this first letter.

Also enclosed is a letter from Kenneth Zuckerman and Albert F. LoBuglio the Director of our Division of Hematology/Oncology showing that it is time for us to return to the routine use of radioactive phosphorous in the treatment of patients with Myeloproliferative Disorders because it has been proven to be safer and more effective than the most popular treatment today, namely, chlorambucil.

Sincerely,

William H. Beierwaltes

William H. Beierwaltes, M.D.
Professor of Medicine
Director, Division of
Nuclear Medicine

WHB:js

Enclosures

cc: Joseph F. Ross, M.D.

UNIVERSITY HOSPITAL

July 28, 1980

Joseph F. Ross, M.D.
The American Board of
Nuclear Medicine
900 Veteran Avenue
Los Angeles, California 90024

Dear Joe:

Thank you for your letter of July 14, 1980 regarding retaining therapy in Nuclear Medicine.

I write to tell you that I will write the N.R.C. today.*

Also, I am enclosing a very important document from Kenneth Zuckerman and Al LoBuglio to me regarding ^{32}P and the treatment of myeloproliferative Disorders.

I will also send this to the N.R.C..

The great importance of the Nuclear Medicine approach to therapy is that if we can bring this approach off with other radionuclide labeled compounds in other cancers, this approach might totally out mode modern radiation therapy and chemotherapy as it is currently practiced by Radiology and Internal Medicine.

The basis for this remark is that in 34 years of treating 560 patients for thyroid cancer with radioactive iodine, we have had no increased incidence of leukemia or second cancers.

On the other hand, Chabner in an editorial in the New England Journal of Medicine Vol. 297 page 212, 1977, entitled "Second Neoplasm - A complication of cancer chemotherapy" reviews the fact that in ovarian cancer patients living two years after initiation of chemotherapy the risk of developing acute leukemia is increased by a factor of 67 to 171. Similarly, in patients with Hodgkins Disease the risk of developing a second cancer four years after nodal radiation and chemotherapy is increased by a factor of 21. That is why this letter from the head of our cancer division to me showing that Chlorambucil causes an increased incidence of leukemia in patients with polycythemia vera where as there is no evidence that radioactive phosphorous does is one of the first major steps in recognizing the advantage of treatment with internally administered radionuclides over conventional chemotherapy and radiation therapy.

We are also currently evaluating the therapeutic potentials of a new radioiodine labeled metaiodobenzylguanidine which we believe is the ultimate

adrenal medulla imaging agent. If it concentrates therapeutically in pheochromocytomas and neuroblastomas, our experience in treating thyroid cancer will be an important predictor of the future. Similarly, we start our first therapeutic trials in the treatment of a human choriocarcinoma in a syrian hamster cheek pouch with radioiodine labeled monoclonal antibodies to HCG.

Since it is obvious that therapy in Nuclear Medicine is increasing rather than decreasing, and since it is obvious that therapy with the use of internally administered radionuclides involving sophisticated immunology and biochemistry is here it is even more important that therapy not be dropped from Board requirements in Nuclear Medicine.

Sincerely,

William H. Beierwaltes, M.D.
Professor of Medicine
Director, Division of
Nuclear Medicine

WHB:js

Enclosure

* Copy of letter enclosed

FOR INTRA-UNIVERSITY CORRESPONDENCE

H. Heff 7-22-80

THE UNIVERSITY OF MICHIGAN

MEMORANDUM Heff 7-23-80

TO: William Beierwaltes, M.D.
Director, Division of Nuclear Medicine

FROM: Kenneth Zuckerman, M.D. K. Zuckerman 763-4042
Division of Hematology/Oncology

Albert F. LoBuglio, M.D. A F LoBuglio
Director, Division of Hematology/Oncology

RE: Use of Radioactive Phosphorous (^{32}P) in the treatment of Patients with Myeloproliferative Disorders

DATE: July 9, 1980

^{32}P has been used for several decades as one of the major modes of therapy of patients with polycythemia vera and other myeloproliferative disorders, and it has been proven to be an effective therapeutic modality. Because of reports many years ago of an increased incidence of acute leukemia complicating patients treated with ^{32}P, many hematologists began using alkylating agents in place of ^{32}P. However, an increased incidence of acute leukemia has also been reported in patients with myeloproliferative disorders who received these agents. In order to resolve the question of the best therapy of patients with polycythemia vera, a large cooperative group has studied approximately 450 patients with polycythemia vera, who have been divided into treatment groups comparing phlebotomy alone, alkylating agent (Chlorambucil) plus phlebotomy, or ^{32}P plus phlebotomy. There is currently a minimum follow-up of 5 years on 134 to 156 patients in each group. The results, which were reported at the meeting of the American Society for Hematology in December 1979, were as follows. 1 of 134 patients in the phlebotomy group had developed leukemia, whereas 15 of 141 patients on Chlorambucil and 6 of 156 patients on ^{32}P have developed acute leukemia. Extensive statistical analysis demonstrated that this difference in leukemia incidence was significant and that it could be attributed to no known factor other than treatment with Chlorambucil. As a result of this finding Chlorambucil therapy has been stopped in this group's therapeutic trials. These results are widely accepted among hematologists, and a broad consensus of opinion is that the current treatment of choice in polycythemia vera, and probably in other myeloproliferative disorders, is now ^{32}P.

It is our feeling that if we are to be able to treat patients with myeloproliferative diseases optimally, exposing them to the least possible risk of acute leukemia, and in all likelihood increasing their survival and decreasing their morbidity, it is necessary that ^{32}P be available for the treatment of these patients. Although it is difficult to estimate the useage of ^{32}P at this institution, it would in all likelihood be greater than 10 doses and fewer than 50 3 to 5 millicurie doses per year. We are hopeful that the Nuclear Medicine Division could obtain and administer this agent. We will also be happy to help the Division of Nuclear Medicine in acquiring the drug if such assistance is necessary.

CC: William N. Kelley, M.D.
Jeptha W. Dalston, Ph.D.

UNIVERSITY HOSPITAL

June 30, 1980

Joseph F. Ross, M.D.
Secretary,
The American Board of Nuclear Medicine
11246 Cashmeir Street
Los Angeles, California 90049

Dear Joe:

As you know, I have heard rumors that some people want to take therapy out of Nuclear Medicine as a requirment for the board.

I oppose this since I get about four phone calls a day from four Doctors in four different States of the Union routinely asking me questions on how to treat well-differentiated thyroid cancer with radioactive iodine. I also get a few requests from Doctors on how to treat specific cases of Hyperthyroidism with radioiodine.

In our own training program we find in mandatory to have three examining rooms where our trainees can do a complete history and physical examination on every new thyroid patient who is to be considered for radioiodine treatment.

The initial requirements of competence in a Nuclear Medicine physican stressed that the physican should be able to a history and physical examination, survey all of the necessary data to arrive at a proper diagnosis and also to treat the patient.

We treat about 31 new cases of thyroid cancer a year in our Nuclear Medicine Division and about 300 cases of hyperthyroidism.

We have a therapy conference from 1-2 P.M. on Wednesdays routinely which is acredited for C.M.E. credits.

No matter whether our trainees end up as Professors of Radiology or any other Department in which they in the Nuclear Medicine Division, they constantly call us for advice on how to treat patients. My most recent call was from Paul Hoffer, M.D., Director of Nuclear Medicine at Yale University.

Furthermore, if our new ^{131}I-metaiodobenzylguanidine shows the same concentrati of radioiodine in the pheochromocytoma or the neuroblastoma, that it does in the normal adrenal medulla, we will be treating pheochromocytomas like we now treat Grave's Disease with radioiodine and will be treating neuroblastomas (the second most common cause of death from the cancer in a child) like we now treat well-differentiated thyroid carcinoma.

Sincerely,

Bill B

William H. Beierwaltes, M.D.
Professor of Medicine
Director, Division of Nuclear Medicine

WHB:js

Attachment, ANM State [illegible] on
Therapy

(2)

POOR ORIGINAL

THE AMERICAN BOARD OF NUCLEAR MEDICINE

INCORPORATED 1971

A CONJOINT BOARD ORGANIZED WITH THE SPONSORSHIP OF THE AMERICAN BOARD OF INTERNAL MEDICINE, AMERICAN BOARD OF PATHOLOGY, AMERICAN BOARD OF RADIOLOGY AND THE SOCIETY OF NUCLEAR MEDICINE HEREBY CERTIFIES THAT

HAS MET THE REQUIREMENTS OF THIS BOARD AND IS CERTIFIED AS QUALIFIED TO PRACTICE AS A SPECIALIST IN ALL ASPECTS OF CLINICAL AND LABORATORY

NUCLEAR MEDICINE

INCLUDING BUT NOT LIMITED TO RADIOBIOASSAY, NUCLEAR IMAGING, IN VIVO MEASUREMENTS AND THERAPY WITH UNSEALED RADIONUCLIDES

CHAIRMAN

SECRETARY

NUMBER 01221

DATE MAY 5, 1972

The American Board of Nuclear Medicine

A CONJOINT BOARD OF THE AMERICAN BOARDS OF INTERNAL MEDICINE, PATHOLOGY AND RADIOLOGY SPONSORED BY THE SOCIETY OF NUCLEAR MEDICINE

900 Veteran Avenue Los Angeles, California 90024 Telephone (213) 825-6787

JOSEPH E. ROSS, M.D.
Executive Director

July 20, 1980

Mr. Richard Cunningham, Director
Division of Fuel Cycle & Material Safety
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

SUBJECT: Comments of the American Board of Nuclear Medicine concerning the qualifications of diplomates of the American Board of Nuclear Medicine for licensure for administration of radionuclides to human individuals for therapeutic purposes (categories #4 and #5).

Dear Mr. Cunningham:

Provided is a brief statement made on behalf of the American Board of Nuclear Medicine in regard to the therapeutic uses of radionuclides by physicians who are certified by the American Board of Nuclear Medicine as specialists in the broad field of nuclear medicine. It is hoped that this will be sent to members of the Advisory Committee on Medical Uses of Isotopes for their perusal prior to their anticipated meeting on 8/18/80.

It is anticipated that Dr. Mathews B. Fish, Chariman of the American Board of Nuclear Medicine will present this material before the Advisory Committee on Medical Uses of Isotopes at the time of the meeting. It is anticipated that Dr. Fish also will make comments in regard to the general requirements for license of individuals for the use of radioactive materials in human individuals. His comments in this regard will supplement those which he presented to the Advisory Committee on January 18, 1980.

Thank you for your kind consideration.

ATT[redacted]0. 3

Training and Experience Criteria
Page 20 of 105

Very sincerely yours,

Joseph F. Ross, M.D.

cc: Dr. Mathews B. Fish
ABNM Members
Mr. Larry Camper
Mrs. Patricia Vacca
Dr. William R. Hendee, President, SNM
Dr. Herbert Allen, President, ACNM
Dr. Robert O'Mara, President, ACNP
Mr. Henry Ernsttahl, Executive Director, SNM
Dr. William MacIntyre, President, FCNMO
Dr. Richard Peterson
Dr. Peter Schneider

Encls.

JFR/dsr

STATEMENT OF MATHEWS B. FISH, M. D.

ON BEHALF OF

THE AMERICAN BOARD OF NUCLEAR MEDICINE

BEFORE

THE NUCLEAR REGULATORY COMMISSION'S

ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

PREPARED BY JOSEPH F. ROSS, M.D.
EXECUTIVE DIRECTOR, ABNM

SILVER SPRINGS, MARYLAND

AUGUST 18, 1980

ATTACHMENT NO. 3

Training and Experience Criteria
Page 22 of 105

AMERICAN BOARD OF NUCLEAR MEDICINE

Statement presented to The Nuclear Regulatory Commission's

Advisory Committee on Medical Uses of Isotopes

August 18, 1980

Silver Springs, Maryland

Qualification of physicians certified by the American Board of Nuclear Medicine (ABNM) as specialists in nuclear medicine for licensure by the Nuclear Regulatory Commission for therapeutic administration of radioactive materials to humans.

Introduction

The qualifications of Dr. Fish and the activities and concerns of the ABNM were detailed in the presentation to the Advisory Committee made by the ABNM on January 18, 1980. They will not be repeated here.

The ABNM recommends to the Nuclear Regulatory Commission (NRC) Advisory Committee on Medical Uses of Isotopes (ACMUI) that physicians certified by the ABNM as specialists in nuclear medicine be recognized by the NRC as having satistied its requirements for licensure for the therapeutic use of radioactive materials in Categories #4 and #5 in humans. It is the opinion of the Board that diplomates of the ABNM qualify for this licensure for the following reasons:

Training and Experience

Training and experience in therapeutic use of radionuclides meets or exceeds the requirements of the Nuclear Regulatory Commission for such use.

(A) A survey of training in therapy provided residents during the 2 years of residency in LCGME approved nuclear medicine residency training programs reveals that these programs provide experience in administering and observing radioisotope therapy during the 2 years of their training as follows:

	Number of patients treated per program during 2 years	
	Range	Average
Total number of patients treated	20-392	150
Treatment of hyperthyroidism	16-308	120
Treatment of thyroid cancer	2-80	21
Effusions	0-16	
Other therapy	0-38	

It is noted that treatment of effusions and "other" treatments are not performed in all training programs. This is attributable to the fact that such therapies are not accepted as the most desirable modality of treatment by several program directors

(B) Experience in diagnosis, treatment, and management of patients evaluated for and treated with radioactive materials, and in formal didactic instruction and laboratory experience amounts in different programs to between 125 and 350 hours during the 2 years of training. This range indicates the variability of patient load in the several hospitals and clinical settings. Additionally, there is a minimum of 6 months required training in basic science relevant to treatment: eg. radiation biology, radiation chemistry, radiopharmacology, radiation

safety, etc.

(C) Prior to the establishment of nuclear medicine training programs and the requirement in 1977 of 2 years of residency training in LCGME approved residencies, candidates for the American Board of Nuclear Medicine certifying examination were required to demonstrate that they had had between 5 and 10 years of experience in the practice of nuclear medicine. The subject of whether or not such candidates had adequate experience in therapeutic application of radionuclides was discussed with Dr. Merrill Bender, Chairman of the ABNM or of the ABNM Credentials Committee, during the period 1971-1978, and a former member of the Nuclear Regulatory Commission Advisory Committee on Medical Uses of Isotopes. Dr. Bender states that the candidates during this period had experience in therapeutic administration of radioactive materials which was equivalent to or exceeds that now being received by residents in nuclear medicine training programs. In Dr. Bender's opinion physicians certified by the ABNM 1972 through 1976 meet or exceed the NRC requirements for licensure for therapeutic use of radionuclides.

The ABNM Certifying Examination

The ABNM Certifying Examination is a 7 or 8 hour duration written objective-type examination which consisted of 300 questions until 1978 at which time the number of questions was reduced to 250 and the duration of the examination from 8 hours to 7 hours. Twenty-two percent of the examination questions have related to the basic science aspects of nuclear medicine, and to therapeutic applications of radionuclides. The basic science questions are related to medical nuclear physics, radiation biology, radiation protection, instrumentation, radiopharmaceutical chemistry, statistics, and computer sciences. A quarter of this twenty-two percent of the examination has dealt specifically with the clinical aspects of treatment with radionuclides. In other words, 5 to 6 percent of the total examination questions specifically have been concerned with therapy. These questions have

related to the clinical indications and contraindications for radionuclide therapy; the possible hazards of such therapy· the dosage determination for appropriate therapeutic application; the expected radiation effects of such therapy; the potential benefits and disadvantages of radionuclide therapy in comparison with other modalities of treatment for the disease condition under consideration; the methodologies to be employed in the therapeutic administration of radionuclides; and the management of patients who have received such treatment.

Certification by the ABNM

The American Board of Nuclear Medicine specifically certifies its diplomates in the therapeutic use of unsealed sources of ionizing radiation. It is the only certifying board that issues such special certification.

CONCLUSION

As summarized above by reason of training, experience, and satisfactory completion of a rigorous certifying examination, diplomates of the American Board of Nuclear Medicine are qualified to be licensed for the therapeutic uses of radioactive materials.

(13)

Use of Iodine 131 for Treatment of Cardiac Dysfunction

Option 1 of 3

FDA has reclassified the use of iodine-131 for treatment of cardiac dysfunction as lacking substantial evidence of effectiveness. NRC's Advisory Committee on the Medical Uses of Isotopes recommends that the Commission:

DELETE THE USE OF IODINE-131 FOR THERAPEUTIC TREATMENT OF CARDIAC DYSFUNCTION FROM GROUP IV OF 10 CFR 35.100.

Basis for the Recommendation:

Physicians will still be able to perform this treatment, but will have to do so under a physician- or manufacturer-sponsored "Notice of Claimed Investigational Exemption for a New Drug" (IND) that has been accepted by FDA.

FDA and NRC can work together to expedite an IND and license amendment when emergency treatment is necessary.

By using the IND process, physicians will eventually establish or disprove evidence of effectiveness for this treatment.

Deletion of this treatment is consistent with NRC's Medical Policy Statement which states that: "NRC will continue to restrict the uses of therapeutic and certain diagnostic radioactive drugs to the indicated procedures that have been approved by FDA."

CARDIAC DYSFUNCTION

Use of Iodine 131 for Treatment of Cardiac Dysfunction

Option 3 of 3

FDA has reclassified the use of iodine-131 for treatment of cardiac dysfunction as lacking substantial evidence of effectiveness. NRC's Advisory Committee on the Medical Uses of Isotopes recommends that the Commission:

RETAIN THE USE OF IODINE 131 FOR THERAPEUTIC TREATMENT OF CARDIAC DYSFUNCTION IN GROUP IV OF 10 CFR 35.100, BUT LIMIT THE TREATMENT TO CASES IN WHICH IT IS THE PREFERRED METHOD OF THERAPY AND IN WHICH THE POTENTIAL BENEFITS TO THE PATIENT FAR EXCEED THE RISK.

Basis for the Recommendation:

FDA's action was based on lack of evidence of effectiveness (not evidence of ineffectiveness or patient safety considerations).

The rare use of this treatment prohibits gathering evidence of effectiveness for the following reasons:

a) Manufacturers do not have a financial incentive to perform adequate clinical trials.

b) Individual physicians do not have the time and monetary resources to perform adequate clinical trials.

c) Investigators do not have enough patients for adequate and well controlled studies.

FDA's action does not prevent physicians from using this treatment. FDA removed cardiac dysfunction as an indication for use on the official product labeling. Under FDA policy, the individual physician can determine whether or not the benefit-risk of using a particular drug in a particular patient is justified.

Deletion would remove this therapy from the physician's options in cases where other treatments are not effective and could therefore jeopardize some patients.

8/1/80 DRAFT.

(13) (14)

NUCLEAR REGULATORY COMMISSION

10 CFR PART 20

BIOMEDICAL WASTE

AGENCY: U.S. Nuclear Regulatory Commission (NRC)

ACTION: Final Rule

SUMMARY: The NRC is amending its regulations to permit licensees greater leeway in disposing of liquid scintillation media and animal carcasses containing tracer levels of hydrogen-3 (tritium) or carbon-14.

Licensees are now required to dispose of these items by sending them to a radioactive waste burial ground or by obtaining special authorization from NRC for incineration or onsite burial. Under the amended regulations, the licensee may dispose of these materials without regard to their radioactivity. These amendments will also raise the limit for disposal of hydrogen-3 and carbon-14 by release to the sanitary sewerage system.

EFFECTIVE DATE: (insert date of publication)

FOR FURTHER INFORMATION CONTACT: John R. Cook, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555 (Telephone: 301-427-4240).

SUPPLEMENTARY INFORMATION: Radionuclide tracers are used extensively in biomedical research and for the diagnosis of diseases in humans. One of the

end products of these research and medical activities is radioactive wastes. Typically, these wastes are either shipped to radioactive waste burial grounds or, for certain water soluble or dispersible wastes, are released into sanitary sewerage systems. Two of the most commonly used radioisotopes in biomedical research (and to a lesser extent in medical procedures) are hydrogen-3 and carbon-14. The concentrations of these radionuclides in biomedical waste are minute, generally less than 0.05 microcuries per gram.

Liquid scintillation media and animal carcasses, both containing tracer quantities of hydrogen-3 or carbon-14, are the largest volume of radioactive biomedical waste.

Liquid scintillation counting has become a widespread technique for detecting radioactivity in biological samples such as blood or urine. Typically, a fraction of a milliliter of the biological sample containing tracer levels of hydrogen-3 or carbon-14 is combined with 20 milliliters or less of an organic solvent such as toluene or dioxane in a small vial to make a liquid scintillation medium. The vial is placed in a liquid scintillation counter, and the biological sample is assayed. The vials are used once and then collected and shipped to a radioactive waste burial ground.

Research laboratories and hospitals throughout the country are using approximately 84 million vials per year which represents 200 thousand gallons of liquid scintillation media. Disposal of this waste in radioactive waste burial grounds requires approximately 390 thousand cubic feet

at a cost of over $12 million per year. Liquid scintillation media are approximately 40% of the total volume of radioactive waste shipped to burial grounds that is not related to nuclear power generation and its supporting fuel cycle.

Animals are used mainly in research for the development and testing of new drugs. Virtually every chemical compound that is considered for use as a human or veterinary drug is first tagged with a hydrogen-3 or carbon-14 tracer and injected into research animals to study how the chemical compound behaves in a higher life form. These research animals include mice, rats, dogs, monkeys, swine, and sheep. The animal carcasses containing trace quantities of hydrogen-3 and carbon-14 are usually shipped to radioactive waste burial grounds. Animal carcasses require 80 thousand cubic feet of burial space at a cost of almost $4 million per year. Animal carcasses are approximately 10% of the total volume of radioactive waste shipped to burial grounds that is not related to nuclear power generation and its supporting fuel cycle.

There are other hydrogen-3 and carbon-14 waste streams in the research laboratory that do not result in liquid scintillation vials and animal carcasses; for example, the solutions and attendant material used to prepare the research samples and animal excreta and contaminated bedding. These materials are also contaminated with tracer levels of hydrogen-3 and carbon-14.

Under present NRC regulations, hydrogen-3 and carbon-14 wastes that are readily soluble or dispersible in water are disposed of by release to the sanitary sewerage system. The annual limit for release to the sanitary sewerage system is found in 10 CFR 20.303 and is a total of 1 curie of all radionuclides. Raising the limit for hydrogen-3 to 5 curies per year and for carbon-14 to 1 curie per year is a negligible addition to the radioactivity present in the natural environment.

There are alternatives for disposal of liquid scintillation media and animal carcasses containing hydrogen-3 and carbon-14 other than consignment to a radioactive waste burial ground. Liquid scintillation media can be evaporated, distilled, burned or consigned to a chemical waste burial ground. Animal carcasses can be incinerated in a pathogen incinerator. Currently, none of these alternatives to radioactive waste burial are easily available under NRC's regulations. Essentially, 10 CFR 30.41 and 10 CFR 20.301 of NRC's regulations and similar Agreement State regulations require that liquid scintillation media and animal carcasses with any added hydrogen-3 or carbon-14 be handled as radioactive waste and consigned to a radioactive waste burial ground. This costs hospitals and research institutions about $16 million per year.

The state agencies that control the existing radioactive waste burial grounds do not want to accept liquid scintillation media or animal carcasses. Liquid scintillation media are flammable and are suspected of leaching radioactive chemicals out of the burial trenches. Also, some of the shipping

containers arrive at the burial grounds leaking. Liquid scintillation media are chemically toxic and carcinogenic and thus pose a waste hazard unrelated to their radioactive character. Animal carcasses decompose and are a pathogen hazard. Sometimes the animal carcasses will cause their containers to burst during shipment.

The three radioactive waste burial grounds in the U.S. are located in Barnwell, South Carolina; Beatty, Nevada; and Richland, Washington. Only the Richland, Washington site accepts both liquid scintillation media and animal carcasses. The Beatty, Nevada site accepts only animal carcasses and the Barnwell, South Carolina site does not accept either liquid scintillation media or animal carcasses. At all three sites, the state regulatory bodies and owners are attempting to reduce the volume of incoming waste to prolong site use.

During a temporary state-imposed embargo in mid-1979, some hospitals and research institutions across the country came within days of curtailing operations involving liquid scintillation counting and animal research before the radioactive waste burial ground in Richland, Washington, resumed accepting liquid scintillation vials and animal carcasses, and the radioactive waste burial ground in Beatty, Nevada, resumed accepting animal carcasses. Such wastes are being accepted at these two locations reluctantly, and mainly because of the medical crisis that would follow from their refusal to do so.

The Rule

Essentially, this rulemaking will allow NRC licensees to dispose of liquid scintillation media and animal carcasses containing less than 0.05 microcuries of hydrogen-3 or carbon-14 per gram without regard to their radioactivity. This regulation will not relieve licensees from complying with other applicable regulations of Federal, state and local government agencies regarding the disposal of non-radioactive materials. Scintillation media are toxic and flammable, and animal carcasses are pathogenic. These characteristics, which are a more important public health problem than their radioactivity, require them to be disposed of under applicable Federal, state and local laws governing chemical and biological hazards. This rulemaking will also allow the disposal by release to a sanitary sewage system of up to 5 curies of hydrogen-3 and 1 curie of carbon-14 per year in addition to the presently allowed 1 curie per year for all radionuclides.

Because the amount of hydrogen-3 and carbon-14 that could be released to the environment as a result of this rulemaking is much less than natural levels, and because the probable dose to any individual is less than 1 millirem per year, the Commission concludes that the rulemaking will have no adverse impact on the environment. Basically, from a radiological health standpoint, it does not matter whether NRC requires burial of this waste or releases it from NRC regulatory controls.

The rule essentially removes any NRC restrictions on the disposal of liquid scintillation media and animal carcasses. It will no longer be necessary for

NRC licensees to ship these materials, which pose a chemical and biological hazard, up to thousands of miles across the country for disposal in a radioactive waste burial ground. NRC Agreement States may make similar amendments to their regulations in order to extend the benefit of this action to their licensees. The states of ... and ... presently permit disposal of liquid scintillation media and animal carcasses without regard to their radioactivity.

The value/impact analysis supporting this rulemaking is available for public inspection at the Commission's Public Document Room at 1717 H Street, N.W., Washington, D.C., 20555. Single copies may be obtained from John R. Cook. The value/impact analysis concluded that this rule change was the best solution to the problem of disposal of liquid scintillation media and animal carcasses containing tracer amounts of hydrogen-3 and carbon-14. The value/impact analysis shows that the action is non-substantial and insignificant from the standpoint of environmental impact. If also adopted by the Agreement States, this action will save hospitals and research institutions $13 million ($16 million for the cost of radioactive waste disposal minus the $3 million it will cost for non-radioactive waste disposal) dollars per year. More importantly, it will save almost one-half million cubic feet of radioactive waste burial capacity or half of that used for radioactive waste not related to nuclear power generation and its supporting fuel cycle.

In summary, amendments concerning the tracer levels of hydrogen-3 and carbon-14 in liquid scintillation media and animal carcasses are appropriate because:

(a) they will not harm the public if they are released from NRC regulatory controls; (b) disposal of these wastes in radioactive waste burial grounds is expensive; (c) the flammability of liquid scintillation media (organic solvents) and the decomposition of animal carcasses cause a significant problem in transporting these wastes to burial grounds; and (d) these wastes consume a significant portion of radioactive waste burial capacity which is in short supply.

Similarly, the amendment raising the limit for sanitary sewerage disposal of hydrogen-3 and carbon-14 is appropriate because this action will not harm the public, and shipment to radioactive waste burial grounds is both costly and consumes valuable burial space that should be made available for more hazardous radioactive waste.

The Commission has decided that good cause exists to make it unnecessary and contrary to the public interest to seek public comment. In making this decision, the Commission has concluded that delaying the rule for public comment would be contrary to the public interest due to (1) the serious disruption of medical services that could result from the closing of the radioactive waste burial grounds to these wastes furing the comment period; (2) the continued cost for shipping to burial grounds during the comment period; and (3) the consumption of disposal capacity during the comment period. Further, through its Advisory Committee on the Medical Uses of Isotopes and its professional consultants, the Commission has gathered sufficient information to know the extent of the problem and the range of possible solutions. In view of the pressing need for action in the short term, the

Commission doubts that public comment would change either the perceived need for the rule nor the method of implementation. However, the Commission recognizes the value of public comment in correcting any oversights or defects in this final rule in terms of its application in the long term and invites comments for this purpose. Accordingly, written comments or suggestions on the final rule should be submitted to the Secretary of the Commission, U. S. Nuclear Regulatory Commission, Washington, D. C. 20555, Attention: Docketing and Service Branch. Copies of comments received may be examined at the Commission's Public Document Room at 1717 H Street, N. W., Washington, D. C.

In addition, because this substantive rule serves to relieve a restriction on the transfer of licensed material imposed by 10 CFR 30.41, the publication of this rule 30 days before its effective date is not required. Therefore, the rule is being published effective immediately.

Under the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and Sections 552 and 553 of Title 5 of the United States Code, the following amendments to Title 10, Chapter I, Code of Federal Regulations, Part 20, are published as a document subject to codification.

PART 20-STANDARDS FOR PROTECTION AGAINST RADIATION

1. Section (c) of §20.301 is revised to read as follows.*

§20.301 General requirement.

* * * * *

(c) As provided in §20.303 or §20.304, applicable respectively to

*Additions to the present rule are underlined.

the disposal of licensed material by release into sanitary sewerage systems or burial in soil, or in §20.306 for disposal of specific wastes, or in §20.106 (Radioactivity in effluents to unrestricted areas).

* * * * *

2. Section (d) of §20.203 is revised to read as follows:

§20.303 Disposal by release into sanitary sewerage systems.

* * * * *

(d) The gross quantity of licensed and other radioactive material, excluding hydrogen-3 and carbon-14, released into the sewerage system by the licensee does not exceed one curie per year. The quantities of hydrogen-3 and carbon-14 released into the sanitary sewerage system may not exceed 5 curies per year for hydrogen-3 and 1 curie per year for carbon-14. Excreta from individuals undergoing medical diagnosis or therapy with radioactive material shall be exempt from any limitations contained in this section.

* * * * *

3. §20.305 is revised to read as follows:

§20.305 Treatment or disposal by incineration.

No licensee shall treat or dispose of licensed material by incineration except for materials listed under §20.306 or as specifically approved by the Commission pursuant to §§20.106 (b) and 20.302.

* * * * *

4. A new §20.306 is added to read as follows:

§20.306 Disposal of specific wastes

Any licensee may dispose of the following licensed material without

regard to its radioactivity:[1]

(a) 0.05 microcuries or less of hydrogen-3 or carbon-14, per gram of medium, used for liquid scintillation counting; and

(b) 0.05 microcuries or less of hydrogen-3 or carbon-14, per gram of animal tissue; provided however, tissue may not be disposed of under this section in a manner that would permit its use either as food for humans or as animal feed.

* * * * *

[Sec. 161b, Pub. L. 83-703, 68 Stat. 948 (42 U.S.C. 2201), Sec. 201, Pub. L 93-438, 88 Stat. 1242 (42 U.S.C. 5841)]

Dated at Washington, D.C., this _____ day of _____.

FOR THE NUCLEAR REGULATORY COMMISSION

Samuel J. Ch k
Secretary of the Commission

[1]This provision does not relieve any person from complying with other applicable regulations of Federal, state and local government agencies regarding the disposal of non-radioactive materials.

August 7, 1980

Mr. Richard Cunningham, Director
Division of Fuel Cycle and Material Safety
U. S. Nuclear Regulatory Commission
Washington, D.C. 20555

Dear Sir:

It has recently come to my attention that your agency is holding hearings into the licensure of physicians for the performance of clinical nuclear medicine procedures. In particular, the issue of minimum training requirements for licensure is being considered.

I have been disturbed to find that there is a mounting trend for physicians without primary training in nuclear medicine to obtain N.R.C. licenses by taking brief intensive courses. In particular, nuclear cardiology courses designed to meet minimum requirements, and offered over a six week period have become increasingly popular. In my opinion, this practice poses considerable risks for abuse and ultimately for compromising patient safety. I am concerned because it is unlikely that most physicians would obtain enough basic and practical expertise during such courses to ensure that they could comprehend and intelligently manage all the aspects of nuclear cardiology procedures. The quality assurance and radiation safety aspects would probably be neglected.

I have spent two years of training in a nuclear medicine residency. I perform nuclear cardiology procedures working closely with cardiologists. In general, cardiologists who have even had brief training in nuclear cardiology perform adequately with regard to clinical interpretation, but do not have a comprehensive understanding of quality assurance and radiation safety. I think that adequate preparation would demand at least 12 months of intensive training for most. Therefore, in order to be directly licensed in nuclear cardiology procedures, I think these physicians should certainly have more than just 6 weeks of training.

Respectfully,

David E. Herman, M.D.

David E. Herman, M.D.
5384 Smooth Meadow Way
Columbia, Md. 21044

Medical Center

50 Irving Street, NW.
Washington, D.C. 20422

Veterans Administration

Patricia

August 5, 1980

Richard Cunningham, Director
Division of Fuel Cycle and Material Safety
USNRC
Washington, D. C. 20555

Dear Mr. Cunningham,

The following comments are submitted for the record concerning licensure of physicians whose use of byproduct material is limited to nuclear cardiology. The comments do not necessarily reflect the opinion of this medical center or the Veterans Administration.

The establishment of separate licensure criteria for nuclear cardiologists might be interpreted as tacit approval by the NRC for the establishment of imaging facilities separate from extant nuclear imaging facilities in hospitals. Additional personnel exposure from required daily quality assurance work already being done in an existing department is not consistent with ALARA. Furthermore, there is the distinct possibility of an inordinate increase in the work load of the health physics support staff. Neither the exposure nor the work load would appear to be accompanied by a concomitant increase in the quality of patient care.

Sincerely,

Norman L McElroy

Norman L. McElroy
Radiation Safety Officer

In Reply Refer To:

Medical Center
50 Irving Street, NW.
Washington, D.C. 20422

Veterans Administration

Pat Vacca

August 5, 1980

Richard Cunningham, Director
Division of Fuel Cycle and Material Safety
USNRC
Washington, D. C. 20555

Dear Mr. Cunningham,

The following comments are submitted for the record concerning licensure of physicians whose use of byproduct material is limited to nuclear cardiology. The comments do not necessarily reflect the opinion of this medical center or the Veterans Administration.

The establishment of separate licensure criteria for nuclear cardiologists might be interpreted as tacit approval by the NRC for the establishment of imaging facilities separate from extant nuclear imaging facilities in hospitals. Additional personnel exposure from required daily quality assurance work already being done in an existing department is not consistent with ALARA. Furthermore, there is the distinct possibility of an inordinate increase in the work load of the health physics support staff. Neither the exposure nor the work load would appear to be accompanied by a concomitant increase in the quality of patient care.

Sincerely,

Norman L McElroy
Norman L. McElroy
Radiation Safety Officer

In Reply Refer To:

Medical Center

60 Irving St., N.W.
Washington, D.C. 20422

Veterans Administration

August 9, 1980

Mr. Richard Cunningham
Director, Division of Fuel Cycle
and Material Safety
U. S. Nuclear Regulatory Commission
Washington, D. C. 20555

Dear Mr. Cunningham:

I would like to submit the following statement regarding the coming meeting of the Advisory Committee on the Medical Use of Isotopes on August 18, 1980.

First, I would like to say that the NRC, through its Advisory Committee, has done an admirable job through the years in providing the criteria for licensing physician-users. However, at this point in time, I wonder if consideration should not be given the following.

Should not the Committee consider an increase in the requirements for licensure in lieu of the recent rapid technological advances in Nuclear Medicine? How can one compare a 3 month training period with that required by the American Board of Nuclear Medicine which is a 2 year requirement. Even with a 2 year stint of Nuclear Medicine residency, it is difficult to provide a trainee the necessary training in the basic fundamentals of radiation health, radiopharmaceutical chemistry, instrumentation and computer know-how together with a rounded clinical program.

Moreover, one should consider the mode of training for the potential physician-user. If formal training in basic sciences is condensed into a short type "cram course," how much does a trainee retain? How much exposure and follow-up does one achieve with a clinical training period of 250 hours or even 500 hours? In this condensed period, how much chance does a trainee have to experience an adequate number of differing clinical situations?

Thus, I would advocate the following for your consideration:

1. An increase in the number of training hours in basic science by adding 150 hours to instrumentation, 30 hours to radiation health and 100 hours to radiopharmaceutical chemistry.

2. The time devoted to clinical applications be increased to 750 hours and intersperced with basic training. A preferred equivalent could be 1 year training in an approved Nuclear Medicine Residency training program.

In Reply Refer To:

3. There should be no reduction in training requirements for specialized groups such as cardiology. To do so would fragment Nuclear Medicine, make adequate radiation health coverage difficult, decrease quality control and diminish the effectiveness of clinical applications.

Thank you for the opportunity to express my opinions.

Sincerely yours,

BERTRAM J. L. SAUERBRUNN, M.D.
Chief, Nuclear Medicine Service
VA Medical Center
Washington, D. C. 20422

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AMERICAN COLLEGE OF NUCLEAR MEDICINE
1971

100 Hermann Prof. Bldg.
Houston, Texas 77030

July 30, 1980

Richard E. Cunningham
Director, Division of Fuel Cycle
and Material Safety
Nuclear Regulatory Commission
Washington, D.C. 20555

Dear Mr. Cunningham:

On July 9 we sent to you resolutions approved by the American College of Nuclear Medicine and then sent to the American Medical Association for House of Delegates action during the July 20-24 meeting in Chicago.

The enclosed resolutions were discussed in Reference Committee before referral to the House. After due consideration the attached resolutions were approved.

In the near future you will be hearing from the AMA but because of the urgency of some of these resolutions we are calling them to your attention at this time since the Advisory Committee on the Medical Uses of Isotopes meets Aug. 18, 1980.

Sincerely,

Herbert C. Allen, Jr., M.D.
Immediate Past President ACNM
Delegate AMA

Enclosures
HCA:lr

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 148
(A-80)

Introduced by: The Society of Nuclear Medicine

Subject: Nuclear Regulatory Commission Licensure Requirements for Physicians

Referred to: Reference Committee E
(David S. Fox, M. D., Chairman)

Whereas, The U. S. Nuclear Regulatory Commission presently requires three months combined training and experience for physician licensure to administer radionuclides to patients; and

Whereas, Representatives of the various scientific organizations whose physician members administer radionuclides to patients in the course of their medical practice agree that present licensure requirements for training in such disciplines as radiation safety, radiation biology, radiological physics, nuclear instrumentation and clinical nuclear medicine practice can no longer be encompassed within the present temporal requirement of three months; and

Whereas, The House of Delegates of the American Medical Association, at its Interim Meeting of 1979, adopted Substitute Resolution 42 which states in part ". . . that the American Medical Association support the contention that the current statements of the U. S. Nuclear Regulatory Commission defining minimum requirements for physicians to be eligible to administer radionuclides to patients are unsatisfactory. . ."; and

Whereas, All parties recognize that the U. S. Nuclear Regulatory Commission's licensure process is intended to safeguard patients and the public, and is not intended to comprise certification of professional competence in the practice of medicine; therefore be it

RESOLVED, That the House of Delegates of the American Medical Association recommend to the Nuclear Regulatory Commission that the training requirements for physicians to be eligible to administer radionuclides to patients be raised from its present level of three months to six months; and be it further

RESOLVED, That the AMA urge the U. S. Nuclear Regulatory Commission to continue to require that the training requisite for licensure be documented, and that it contain elements of instruction in radiological physics, radiation biology, radiation safety, nuclear instrumentation, and the safe and effective clinical use of radionuclides in patients; and be it further

RESOLVED, That a copy of this resolution be transmitted by the American Medical Association to the U. S. Nuclear Regulatory Commission prior to the meeting of its Advisory Committee on the Medical Uses of Isotopes on August 18, 1980.

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 128
(A-80)

Introduced by: American College of Nuclear Medicine

Subject: Federal (HHS) Condition for Medical Coverage of Independent Laboratories 3/75 Regulation No. 5

Referred to: Reference Committee E
(John E. Albers, M. D., Chairman)

Whereas, Regulation 405-1310-1315 as published in the Federal Register 3765, January 24, 1975, delineates the conditions for supervision of services of independent laboratories; and

Whereas, These federal standards must be met for reimbursement under Medicare and other federal programs; and

Whereas, These regulations require direct and personal supervision by a qualified "general supervisor" (physician, medical scientist or technologist) when laboratory procedures are being performed on specimens from a patient; and

Whereas, Interpretation of these qualifications for "general supervisors" now exclude recognition of recent in-vitro training and experience in nuclear medicine procedures and exclude those physicians recently trained or certified in the field of nuclear medicine by the American Board of Nuclear Medicine; and

Whereas, Nuclear Medicine has become a recognized specialty with AMA approved programs in which physicians, medical scientists and technologists receive training, experience, and/or examined for certification in the field of nuclear medicine including in-vitro nuclear medicine procedures (radio-immuno assay and radio-bio assay); and

Whereas, The field of nuclear medicine is a recognized specialty with delegate representation in the AMA House of Delegates, the field of nuclear medicine and nuclear medicine laboratories should be recognized by the Department of Health and Human Services as specialty or sub-specialty laboratories; therefore be it

RESOLVED, That the American Medical Association urge the Secretary of Health and Human Services to immediately initiate steps to certify education, training, experience and certification in the field of nuclear medicine as meeting the current requirements for specialty laboratories so that nuclear physicians may qualify as "general supervisors" assisted by medical scientists and technologists in independent laboratories under the Medicare program for reimbursement.

APPROVED AMA HOUSE OF DELEGATES JULY 1980

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 130
(A-80)

Introduced by: American College of Nuclear Medicine

Subject: American Medicine's Responsibility for the Education of the Public and Media of the Biological Effects of Low Level Radiation

Referred to: Reference Committee E
(John E. Albers, M. D., Chairman)

Whereas, The harmful biological effects of high level radiation has been well documented over four score and seven years; and

Whereas, The absolute risk of radiation exposure is so low that it cannot be documented accurately even in large populations exposed to relatively high doses of radiation; and

Whereas, After 30 years' observation in Hiroshima and Nagasaki the total incidence of cancer in those exposed survivors was less than one percent; and

Whereas, No genetic effects could be documented in the first generation offspring of those exposed; and

Whereas, Fear, misunderstanding, phobia and misguided misinterpreted information about radiation by the public and the media should be of great national concern to the medical profession; and

Whereas, The physician seldom is called upon to render an opinion in connection with accidental contamination with radioactive materials or excessive occupational radiation exposures; therefore be it

RESOLVED, That the American Medical Association initiate scientific educational programs at the professional level on the public health aspects of low level environmental radiation to help clarify the national confusion concerning low level radiation; and be it further

RESOLVED, That the American Medical Association immediately encourage these continuing medical educational programs be implemented at the national level and by state medical associations and specialty societies similar to the promotion of the cardiopulmonary resuscitation programs.

APPROVED AMA HOUSE OF DELEGATES July 1980

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 131
(A-80)

Introduced by: American College of Nuclear Medicine

Subject: Nuclear Regulatory Commission Regulation "Human Use of Byproduct Material," 10CFR, Part 35, Published in Federal Register 44 FR 10358, February 20, 1979

Referred to: Reference Committee E
(John E. Albers, M. D., Chairman)

Whereas, Nuclear Regulatory Commission Regulation "Human Use of Byproduct Material," 10CFR, Part 35, effective March 20, 1979, requires that physicians must use an FDA approved drug (radiopharmaceutical) strictly in accord with the manufacturer's package insert as to dose, route of administration and chemical and physical form when using the approved drug in a clinical procedure that has not been approved by the FDA; and

Whereas, This restriction of use of an FDA approved drug as to chemical and physical form, route of administration and dosage range as outlined in the package insert is an unprecedented intrusion into the physician-patient relationship and is in direct opposition to the position of the FDA which permits physicians to use approved drugs according to their best knowledge and judgment and in the interests of the patient; therefore be it

RESOLVED, That the American Medical Association request the Nuclear Regulatory Commission to rescind the regulation requiring a physician to use an approved drug (radiopharmaceutical) in accordance with the manufacturer's package insert as regards chemical and physical form, route of administration and dosage range; and be it further

RESOLVED, That the AMA immediately send this policy statement to the five Commissioners of the Nuclear Regulatory Commission and to the Radiation Policy Council, newly appointed by the Executive Office of the President, composed of 13 agencies of the Federal Government.

APPROVED AMA HOUSE OF DELEGATES JULY 1980

Resolution: 132
(A-80)

Introduced by: American College of Nuclear Medicine

Subject: U. S. Nuclear Regulatory Commission Amendments to Existing Regulations (10CFR Part 35) Reporting Misadministrations of Radiopharmaceuticals to Patients to the Federal Government

Referred to: Reference Committee E
(John E. Albers, M. D., Chairman)

Whereas, During the extensive solicitation of public comment in the Federal Register over 90 percent were opposed to the concept of misadministration reporting to the NCR where the reports would be open to public scrutiny, causing undue alarm; and

Whereas, The NRC chose to issue final rules, proposing amendments to 10CFR Part 35 to require medical licensees to (1) keep records of all misadministrations of radiopharmaceuticals, (2) report diagnostic misadministrations quarterly to NRC, and (3) to promptly report therapy misadministrations to NRC, the referring physician and the patient; and

Whereas, Misadministration is defined in the final rules as the administration of (1) a radiopharmaceutical or radiation from a sealed source other than the one intended, (2) a radiopharmaceutical or radiation to the wrong patient, (3) a radiopharmaceutical or radiation by a route of administration other than that intended by the prescribing physician; (4) a diagnostic dose of a radiopharmaceutical differing from the prescribed dose by more than 50 percent, (5) a therapeutic dose of a radiopharmaceutical differing from the prescribed dose by more than 10 percent, or (6) a therapeutic dose from a sealed source such that errors in the source calibration, time of exposure and treatment geometry result in a calculated total treatment dose differing from the final prescribed total treatment dose by more than 10 percent; and

Whereas, The proposed rule requires the licensee to report all therapy misadministrations and those diagnostic misadministrations that could cause a clinically detectable adverse effect to NRC and to the patient's referring physician, to the patient or to the patient's responsible relative; and

Whereas, The proposed rule is an unprecedented, serious intrusion by a regulatory agency into the physician-patient relationship and into the care of a patient without assuming responsibility for that care under the pretext that such action is necessary to protect the physical health and safety of the public without regard for its ill effect on the mental health of the patient or the public; and

Whereas, This is a unique intrusion into medical practice which was circularized only and not discussed at an open called meeting of the Advisory Committee on Medical Uses of Isotopes of the NRC representing another failure of the administrative staff to consult the entire medical advisory board in open discussion on matters pertaining to the practice of medicine; and

APPROVED AMA HOUSE OF DELEGATES 1980

Whereas, The NRC staff has admitted the rule could increase professional liability insurance premiums, which ultimately would increase the cost of health care; therefore be it

RESOLVED, That the American Medical Association oppose the implementation of amendments of the Nuclear Regulatory Commission's Rules (10CFR Part 35) Requiring Recording and Reporting of Misadministration of Radiopharmaceuticals as illegal intrusion upon the practice of radiology, nuclear medicine and therapeutic radiation which is best left to those who are qualified and licensed to practice medicine, that is, the practitioners themselves; and be it further

RESOLVED, That the AMA send this policy statement to the five Commissioners of the U. S. Nuclear Regulatory Commission, and to the U. S. Radiation Policy Council, newly appointed by the Executive Office of the President, composed of 13 agencies of the federal government.

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 83
(A-80)

Introduced by: Texas Delegation

Subject: Mandatory Reporting to Federal Government of Radiopharmaceutical Misadministrations

Referred to: Reference Committee E
(John E. Albers, M. D., Chairman)

Whereas, The United States Nuclear Regulatory Commission has proposed amendments to 10 CFR Part 35 which would require medical licensees to (1) keep records of all misadministrations of radiopharmaceuticals, (2) promptly report therapy misadministration to NRC, the referring physician and the patient, and (3) to report diagnostic misadministrations quarterly to NRC; and

Whereas, The NRC defines misadministration as the administration of (1) a radiopharmaceutical or radiation from a sealed source other than the one intended; (2) a radiopharmaceutical or radiation to the wrong patient; (3) a radiopharmaceutical or radiation by a route of administration other than that intended by the prescribing physician; (4) a diagnostic dose of radiopharmaceutical differing from the prescribed dose by more than 50 percent; (5) a therapeutic dose of a radiopharmaceutical differing from the prescribed dose by more than 10 percent; or (6) a therapeutic dose from a sealed source, such that errors in the source calibration, time of exposure and treatment geometry result in a calculated total treatment dose differing from the final prescribed total treatment dose by more than 10 percent; and

Whereas, The rules would require the licensee to report all therapy misadministrations and those diagnostic misadministrations that could cause a clinically detectable adverse effect within 24 hours after discovery; and

Whereas, Even though more than 90 percent of the comments on the proposed rules were in opposition to the rules, the NRC has chosen to issue final rules; and

Whereas, Such rules represent an unprecedented and unwarranted intrusion by the federal government in the patient-physician relationship; and

Whereas, The NRC staff has admitted that such rules may well increase professional liability insurance premiums, which would ultimately increase costs to the patients; therefore be it

RESOLVED, That the American Medical Association oppose the implementation of the Nuclear Regulatory Commission's Rules Requiring Recording and Reporting of Misadministration of Radiopharmaceuticals as not being in the best interest of the physician-patient relationship.

AMENDMENT - REPORT OF REFERENCE COMMITTEE E

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Introduced by: Texas Delegation
Frederick J. Bonte, M.D.
Delegate, Society of Nuclear Medicine

(10) RESOLUTION 82 - DISPOSAL OF LOW-LEVEL RADIOACTIVE MEDICAL MATERIALS

Recommend that the following amended Substitute Resolution 82-A be adopted as follows:

RESOLVED: That the American Medical Association inform appropriate officials of the threat to the conduct of bio-medical research and to the delivery of nuclear medicine services, and the concomitant deleterious effects on the health of the citizens of the United States presented by the lack of sufficient numbers of licensed disposal sites for low-level radioactive medical waste materials, and urge that each state act to create a licensed permanent site in-state or to form interstate compacts that will provide for permanent regional disposal sites.