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1 UNITED STATES OF AMERICA
2 NUCLEAR REGULATORY COMMISSION
3 ADVISORY COMMITTEE ON
4 THE MEDICAL USES OF ISOTOPES

5 Holiday Inn
6 8120 Wisconsin Avenue
7 Bethesda, Maryland

8 Friday, May 3, 1985

9 The meeting convened at 9:05 a.m., Richard E. Cunningham,
10 chairman, presiding.

11 COMMITTEE MEMBERS:

12 RICHARD E. CUNNINGHAM, Chairman
13 VINCENT P. COLLINS, M.D.
14 FRANK HOWARD DeLAND, M.D.
15 SALLY J. DeNARDO, M.D.
16 JACK K. GOODRICH, M.D.
17 MELVIN L. GRIEM, M.D.
18 NILO E. HERRERA, M.D.
19 B. LEONARD HOLMAN, M.D.
20 GERALD M. POHOST, M.D.
21 EDWARD W. WEBSTER, Ph.D.
22 DAVID H. WOODBURY, M.D.
23 JOSEPH B. WORKMAN, M.D.

24 CONSULTANTS:

25 PETER R. ALMOND, Ph.D.
WILLIAM H. BRINER, Capt. USPHS (Ret.)

NRC STAFF MEMBERS:

PATRICIA VACCA
NORMAN L. McELROY
GINNY THARPE

C O N T E N T S

	<u>PRESENTATION BY:</u>	<u>PAGE</u>
1		
2		
3	DR. LAWRENCE MUR ⁹ RAFF	10
4	DR. JAMES CHRISTIE	14
5	^{DR.} ROBERT C. SCHLANT	20
6	DR. WILLIAM H. BLAHD	26
7	DR. GEORGE BELLER	34
8	DR. BARRY A. SIEGEL	38
9	DR. K. LANCE GOULD	44
10	DR. KEITH M. LINDGREN	47
11	DR. DANIEL J. GOLDBERG	56
12	DR. JAMES A. RONAN	61
13	^{LAY} DR. LARRY FOX	70
14	DR. MICHAEL WELCH	83
15	DR. ALLAN ROSS	89
16	DR. ROBERT GARCIA	96
17	DR. EDMOND E. GRIFFIN	104
18	DR. PHIL ^{IP} C. JOHNSON	105
19		
20		
21		
22		
23		
24		
25		

P R O C E E D I N G S

MR. CUNNINGHAM: I think we're ready to begin,
ladies and gentlemen.

Good morning, ladies and gentlemen. My name is
Richard Cunningham. I am a member of the Nuclear Regulatory
Commission Staff. I will chair the meeting today.

This meeting of the Advisory Committee on the
Medical Uses of Isotopes is being held in accordance with
the rules and regulations of the General Services
Administration, Title 41, Part ¹⁰⁶ of the Code of Federal
Regulations, ^{and} the rules and regulations of the Nuclear
Regulatory Commission ^{in Title 10,} ~~entitled 2~~ Part 7.

The meeting was announced in the Federal Register
of February 14, 1985.

It was called to order at 9:04.

Let me first start the meeting by introducing the
members of the committee and a few members of the Staff.

I have a hard time seeing down the table, so if
people will raise their hands, so people will know where
they are.

Dr. DeLand, Dr. DeNardo, Dr. Goodrich, Dr. Griem,
Dr. Herrera, Dr. Holman, Dr. Pohost, Dr. Webster,
Dr. Woodbury and Dr. Workman.

We did this in alphabetical order.

With me on my right is Mr. Norm McElroy, who is a

1 DAVbw

1 member of the NRC Staff, and there are other members of the
2 NRC Staff in the audience here, I think. The ones you will
3 recognize are certainly ^{Vandy}~~Don~~ Miller, the Chief of the
4 Materials ~~/~~ Licensing Branch, and Pat Vacca, whom most of you
5 have worked with, in the back. I'd also introduce Ginny
6 Tharpe, who is at the registration desk. Ginny,
7 incidentally, has airlines guides, schedules and that sort
8 of thing that can give you some assistance in changes if
9 changes in travel reservations are necessary.

10 One more thing. We have two important consultants
11 with us today, Dr. Peter Almond, who is our medical physics
12 consultant, and Capt William Briner, radiopharmaceutical
13 consultant.

14 Sorry. That was on a separate list.

15 Before we begin to discuss the topic at hand, a
16 few comments about the function of the committee are in
17 order. The committee advises the NRC Staff on issues and
18 questions that arise from the use of radioactive material
19 for diagnosis. The committee does not direct the Staff, but
20 rather provides counsel. From its inception, the committee
21 has been composed of members from a broad range of
22 specialities, in order to deal with complex issues, cutting
23 across several medical specialties. The committee is
24 composed of members whose primary speciality includes
25 internal medicine, ^{medical}~~radio~~ physics, diagnostic ^N radiology, and

1 DAVbw

1 more recently, cardiology. All have experience in the
2 diagnostic and therapeutic use of radioisotopes. The members
3 come from various types of medical practices and medical
4 institutions. This provides for a diverse background of
5 experience on which the NRC can draw. The members of
6 the committee do not individually represent any medical
7 specialty or professional organization, but are assisting
8 NRC as a member of the committee.

9 The primary purpose of this meeting is to discuss
10 training and experience criteria for physicians who propose
11 to use by-product materials for diagnostic and medical
12 procedures; however, if time permits, the committee will
13 also ask for comments on medical issues.

14 For several years the NRC has had training and
15 experience criteria for physicians who propose to use
16 by-product materials. The criteria are comprised from the
17 training generally believed necessary for the physician to
18 use by-product materials while providing protection for
19 workers, patients and the public from ~~incessive~~ ^{excessive} or
20 unnecessary radiation exposure in accordance with the NRC
21 rules.

22 Until recently, physicians who wanted ~~to~~ ^{to} use
23 by-product materials could satisfy the training criteria by
24 completing an integrated three-month program; however, at
25 several committee meetings held over the years, experts from
26 the medical community said that because of the increase in

1 complexity of the diagnostic interpretation of nuclear
2 medicine studies, the training and basic knowledge of
3 radiation protection had increased.

4 In response, in December 1982, the NRC published a
5 new ~~statement~~^{training} and experience criterion^a that said that the
6 necessary training could be obtained by ~~t~~^taking a formal
7 integrated six-month program. It is important to note that
8 the radiation training criteria were not increased, rather
9 this change reflected the time needed mainly to adequately
10 deal with increased complexity of diagnostic image
11 interpretation.

12 The notice also said a physician who wishes to be
13 authorized for only one or two specific diagnostic
14 procedures may have his training and experience reviewed
15 case by case by the NRC with advice from the committee. In
16 December 1983, the American College of Cardiology ~~published~~^{proposed}
17 alternative criteria for physicians who wanted to perform
18 cardiovascular radiological procedures. Representatives of
19 ~~the~~^{that} organization and several other affected organizations
20 met to discuss several alternative criteria and reported
21 their results of their meetings.

22 There appears to be general agreement on the
23 topics that should be included in the training program.
24 They are described in the Federal Register Notice that
25 announced this meeting.

1 DAVbw

1 It appears the central issue is the operational
2 wording for the duration of integrated programs. All
3 the representatives have endorsed the four-month
4 integrated program for physicians whose use of by-product
5 material would be limited to cardiovascular imaging;
6 however, there appears to be a difference of opinion as
7 to whether the four-month program ^{or} ~~of~~ the six-month program
8 is necessary for those physicians who want to perform
9 nuclear medicine ~~and proceedings~~ ^{procedures.}

10 The duration of integrated programs for
11 cardiovascular imaging, as well as for all other nuclear
12 medicine proceedings is what what we will discuss today.
13 The central question is, how much and what duration of
14 training does a physician need to safely use diagnostic
15 radiopharmaceuticals.

16 One purpose of this meeting is to allow the
17 affected individuals and the public to present ~~their~~
18 thoughts, so they may be taken into consideration by the
19 committee and staff. It thus must be very clear that NRC's
20 authorization ^{of a physician to} ~~on the position~~ use of by-product material for
21 diagnosis and treatment implies that the ^{user's} ~~usage~~ and training
22 is sufficient to avoid unwarranted radiation exposure to the
23 physician, workers and the public, including patients.

24 That authorization does not ^{connote} ~~entail~~ achievement of
25 a particular level of clinical competence. In this sense,
26 the NRC authority is limited to radiological protection,

1 according to its rules rather than the quality of medical
2 practice. We must also be very clear that the public
3 comment process is not a voting mechanism. Rather it is to
4 provide information that should be considered during the
5 regulatory process, that may not be available to the NRC.

6 Although this was stated in the meeting notice, we
7 did receive 100 form letters endorsing a particular
8 proposal. In response to the meeting ~~though~~^{notice,} several
9 persons have asked to make statements. The speakers have
10 been listed on the agenda in the order in which we received
11 the requests to speak. Speakers are reminded that their
12 comments must pertain to the topic at hand. Because of the
13 large number of speakers, I must ask that they limit their
14 comments to five minutes.

15 The full text of the prepared statements will be
16 included with the record of this meeting. The record will
17 be kept open until May 17, 1985 for additional written
18 comments. Questions may only be asked by the committee
19 members and the NRC Staff. This unfortunately, is necessary
20 for the orderly conduct of the meeting in the limited time
21 available.

22 I ask at this time if any of the committee members
23 wish to make further comments in this introductory part.

24 (No response.)

25 MR. CUNNINGHAM: If not, we will start with our

1 first speaker. Before you begin your comments, please
2 identify yourself. Also please state whether or not you are
3 representing an organization or yourself. It should be
4 added that discussions at this meeting are being recorded
5 and a ~~re~~complete transcript will be placed in the Public
6 Document Room.

7 To give you some idea of the order in which you
8 will appear, I'll just run down the list very, very
9 quickly. The first request to speak was from Mr. Linton,
10 but Drs. Christie and Mur^off are going to use that time,
11 followed by Dr. Schlant, substituting for Dr. Williams,
12 Dr. Blahd, Dr. George Beller, substituting for Dr. Ryan,
13 followed by Dr. Siegel, Dr. Gould, Dr. Lin^dgren,
14 Dr. Goldberg, Dr. Ronan, Dr. Lindsay, Dr. Fox, Dr. Martinez,
15 Dr. Welch, Dr. Ross, Dr. Watson, Dr. Griffin and
16 Dr. Johnson.

17 Again I ask you, so that we can move on with this,
18 to make your statements as concise and brief as possible.
19 Certainly, you can add and supplement your statement as much
20 as you wish for the record in this meeting. Incidentally, I
21 might say that the record of this meeting will be very
22 important, because in reaching a decision, a final decision,
23 we have to have the technical, economic and whatever other
24 bases in the record on which we can base any continuation of
25 present criteria or any alterations of criteria for the

1 DAVbw

1 future.

2 DR. GARCIA: I didn't hear my name called.

3 Dr. Garcia, American College of Nuclear Medicine.

4 MR. CUNNINGHAM: I beg your pardon. You're on the
5 list.6 We'll start with Drs. Christie and Muraff, who
7 presumably won't speak together.8 DR. MUR⁹FF: My name is Lawrence Mur⁹ff. I am a
9 practicing radiologist, specializing in nuclear medicine in
10 Tampa, Florida. I'm here as Chairman of the American
11 College of Radiology's Commission on Nuclear Medicine,
12 and I am therefore speaking for the more than 17,000 College
13 members. These radiologists are responsible for the
14 overwhelming majority of nuclear medicine practiced in the
15 United States.16 I am pleased to have the opportunity to submit
17 these comments on the medical use of isotopes. The issue of
18 revised training and experience criteria for physicians who
19 use isotopes for medical purposes has been studied
20 exhaustively since 1979. As the Advisory Committee is
21 aware, the ACR and expert committees have worked for the NRC
22 throughout these discussions to assure that the license
23 requirements for licensure are adequate to protect the
24 public.

25 The NRC mandate is to provide for the safe use

1 ~~of~~ radiation sources ~~and~~ ⁱⁿ medical applications. In that
2 context, the patient and the general public are served best
3 by physicians who are adequately trained in radiation safety
4 procedures.

5 It is imperative that there be no double standard
6 or short cut in training related to safety.

7 ACR believes that the minimum standards for
8 safety should be equally applicable for all users. The
9 hazards associated with the use of by-product materials do
10 not related to the discipline of the physician who
11 administers the isotope. Radiation safety requires equal
12 experience regardless of the isotope application or body
13 system involved.

14 We have pointed out, the residents in radiology
15 and nuclear medicine spend the entirety of their training
16 period working with radiation sources. They receive formal
17 instruction, plus hundreds of hours of practical experience
18 in handling isotopes, calculating doses, implementing safety
19 programs and supervising radiological technologists. This
20 extensive training is necessary to tune into the need for
21 radiation safety as an integral part of every patient
22 procedure. The NRC has appropriately recognized
23 American Board of Radiology certification, diagnostic or
24 therapeutic radiology ^{as} ~~is~~ sufficient to meet safety standards.

25 The ACR is convinced that all physicians who seek

1 full responsibility for the application of radioactive
2 materials should be required to meet minimum standards of at
3 least four months of basic safety training. The fact that a
4 physician may elect to limit his use of isotopes to one part
5 of the body does not detract from the need for a thorough
6 understanding of and competence in comprehensive radiation
7 safety procedures.

8 Safety procedures, in our opinion, do not vary
9 fundamentally from one body system to the other or from one
10 administering physician to the other. The physician who
11 uses isotopes outside of a authorized nuclear medicine or
12 radiology department must accept full responsibility for
13 radiation safety. This is particular^{ly} true for application
14 outside the hospital or an institution in the formal
15 radiation safety program.

16 The ACR participated in two meetings over the past
17 year in an effort to accommodate the interests of all
18 concerned, while recognizing the responsibility of the
19 Nuclear Regulatory Commission. In those meetings the ACR
20 accepted the position that a requirement of four months of
21 radiation safety training, that we feel the requirements for
22 appropriate clinical training are outside this discussion.
23 We feel that Appendix A could be modified, as agreed in
24 those meetings, without threatening the public health and
25 safety.

1 Last fall the Council of the American College of
2 Radiology adopted a resolution setting forth the College's
3 position on training requirements for isotopic use. That
4 resolution, "The ACR agrees to the concept of a four-month
5 training period as part of an approved residency program in
6 radiology, nuclear medicine or cardiology, which includes a
7 minimum of 200 hours of basic science training and 650 hours
8 of clinical training in radionuclide handling should be
9 sufficient to meet Nuclear Regulatory Commission
10 requirements. To ensure public health and safety, the
11 licensure should use all approved Groups 1, 2 and 3
12 radionclides and all approved forms.

13 I thank you for the opportunity to make these
14 comments. I will be happy to answer any of your questions.

15 MR. CUNNINGHAM: Thank you, Dr. Muraff.

16 Do any members of the committee had questions of
17 Dr. Mur^off.

18 Dr. Webster.

19 DR. WEBSTER: Doctor, when you say 200 hours plus
20 650 hours, do you mean a total of 850?

21 DR. MURAFF: We believe these can be accommodated
22 in a concurrent fashion, but within the context of a
23 four-month period.

24 MR. CUNNINGHAM: Thank you, Dr. Mur^off.

25 Dr. Christie.

1 DR. CHRISTIE: Mr. Cunningham, ladies and
2 gentlemen of the committee.

3 I'm Dr. James Christie, Trustee of the American
4 Board of Radiology and Chairman of its Examination
5 Committee. I have been asked by the Trustees of the American
6 Board of Radiology to attend this meeting to present its
7 position concerning the meeting we're having today.

8 The American Board of Radiology was founded in
9 1934 to set minimum standards of competence, especially of
10 radiology, to certify candidates who have demonstrated this
11 competence through examination. In the ensuing 51 years,
12 the American Board of Radiology has examined more than
13 30,000 candidates and certified more than 22,000. At our
14 oral examination in June of this year, the American Board of
15 Radiology will examine 1650 candidates for various branches
16 of radiology.

17 Over the years, the American Board of Radiology
18 through its examination process has undoubtedly dictated to
19 some degree the educational content of training programs.
20 We have not and we will not dictate to our residency
21 programs how this material will be taught.

22 This is not unique to radiology. It is indeed
23 true in all stages of medicine. It is essential that you
24 understand that our residency training programs vary greatly
25 in those strengths and weaknesses, as do our residents, and

1 that only program directors and their faculty understand
2 these strengths and weaknesses and can ~~and~~ make the necessary
3 adjustments.

4 Furthermore, it is essential that you understand
5 that we are teaching in essential five different modalities.
6 And in most instances organ systems and disease processes
7 can be imaged by more than one and occasionally by all of
8 the modalities underlying the resident teaching rotations as
9 a core of learning on the anatomy and pathophysiology of
10 these, which is a critical foundation necessary to use any
11 imaging modality. In order to use this knowledge as a
12 competent radiologist, the resident must learn the specific
13 strengths, limitations and operational weaknesses of each
14 modality.

15 Since there is great overlap as to how a disease
16 process can be imaged, it is immaterial that this core is
17 learned in ultrasound and computer tomography or the nuclear
18 medicine rotation. Therefore, in a program which is
19 strong on computer tomography, for example, the director may
20 well choose to teach this core knowledge there rather than
21 in ultrasound or nuclear medicine.

22 Since there is also a technical overlap in these
23 differnt modalities, such as computer analysis and
24 reconstruction, it is necessary that in the individual
25 modalities, teach only those principles unique to that

1 DAVbw

1 modality.

2 This training, integrated with our physics and our
3 basic science training is usually accomplished in two to
4 three month rotations. Thereafter, resident skills and
5 diagnosis are fine-tuned through the integrated training in
6 the multiple modality simultaneously.

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1 We are convinced that the ability to use and
2 understand all modalities is essential to using one and
3 critical in directing a referring physician to the most
4 useful technique to solve a particular patient problem.

5 Mr. Cunningham, during the last two years and
6 especially during the last year since your new regulations
7 went into effect, the American Board of Radiology and,
8 unfortunately in particular, have literally been bombarded
9 with letters, phone calls, questions at public meetings from
10 department chairmen, program directors, as to what your new
11 requirements entail and how they can be met. These have not
12 been easy questions for me to answer since I and they cannot
13 conceive of how the simple addition of 500 hours of
14 supervised work experience handling radioactive materials
15 can, in any way, contribute to improved public health and
16 safety.

17 Now, since we were satisfied for more than 30
18 years, that three months training coupled with our separate
19 physics and basic science training is sufficient to teach
20 the fundamentals of nuclear energy and to fulfill your
21 mandate to provide for safe use of radioactive sources,
22 medical application^s, it stands to reason that the Board can
23 accept the compromise four-month program

24 If you wish to extend your mandate and dictate
25 additional clinical training, we implore you for the sake of

1 260 program directors and more than 4500 residents in
2 training for which the deadline is fast approaching, to tell
3 us and tell us now and soon, exactly what you want us to do.

4 The practice of medicine in radiology is changing
5 very rapidly and we must be in a position to meet the
6 challenges imposed by these changes. If your requirements
7 are reasonable in the total concept of our training
8 responsibilities we will accept. If they're not reasonable,
9 then the trustees of the American Board of Radiology will be
10 forced to make some very difficult and far-reaching
11 decisions.

12 In considering today, over 80 percent of
13 hospitals in the United States depend mainly upon
14 radiologists with minimum training in nuclear medicine to
15 supervise and interpret nuclear images on a part-time
16 basis; part-time because the work really is insufficient to
17 permit the economic employment of a full-time nuclear
18 radiologist or nuclear medicine physician.

19 I appreciate the opportunity to express our
20 thoughts and concerns today and I'll be happy to answer any
21 questions.

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

24 Do members of the committee have any questions
25 of Dr. Christie?

1 DAVpp

1 (No response.)

2 MR. CUNNINGHAM: I have one question of
3 Dr. Christie.

4 Right at the end you said that you'd have to
5 consider large changes in the way nuclear medicine would be
6 employed if the six-month program is in effect. Now, ^{do} I
7 understand that correctly?

8 DR. CHRISTIE: It depends whether the six-month
9 program is something we can live with. We can't live with
10 the program you designed for us today. If it's a program
11 that we can live with, that we can put into our teaching and
12 not interfere with the teaching of other modalities, then we
13 can accept it. But if it's a six-month program where we're
14 isolated and forced to keep them in the nuclear medicine
15 laboratory for six months, I doubt very much we can accept
16 this.

17 MR. CUNNINGHAM: The idea being that they get at
18 least part of this training in other areas.

19 DR. CHRISTIE: Of course. And we teach all of
20 these things as integrated within a spectrum. We don't
21 teach nuclear medicine in a vacuum. We don't teach
22 ultrasound in a vacuum. We do for a short period of time in
23 order to familiarize people with the equipment and
24 everything else.

25 But thereafter to isolate these people, it

1 wouldn't make any difference what imaging modality we'd
2 ask them do to. If we put them in ultrasound and kept them
3 just within ultrasound an additional three months, it would
4 be a terrible waste of their time. They should be
5 integrating this material with all other material.

6 And, as I said, it makes no difference whether we
7 learn cardiology or the pathophysiology of cardiac disease.
8 Whether we learn that from the angiographics or nuclear
9 medicine or learn that in ultrasound, the anatomy is the
10 same; the physiology is the same; the diseases are the
11 same. All we're doing is looking at them differently.

12 MR. CUNNINGHAM: Thank you very much.

13 Dr. Schlant?

14 DR. SCHLANT: Mr. Cunningham, Members of the
15 Advisory Committee, my name is Robert C. Schlant, Professor
16 of Medicine and Director of the Division of Cardiology at
17 Emory University School of Medicine.

18 Since 1982 I've been the chairman of a joint task
19 force of the American College of Cardiology and the American
20 Heart Association looking at the matters of nuclear
21 cardiology issues. I'm also testifying today on behalf of
22 this task force and on the American College of Physicians.

23 Our task force has reviewed in detail the
24 questions of the duration of training necessary for
25 physicians ^Lsafely to use radioisotopes in nuclear
26 cardiology.

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1 We've spoken with many specialists in nuclear
2 cardiology and many directors and trainees. We've
3 considered the cost, duration and content of training in
4 cardiology and proposed training and experience requirements
5 for physicians performing nuclear cardiology.

6 Our conclusions are based upon what we would
7 consider to be appropriate but safe applications of
8 radioisotopes and for the protection of public safety.

9 We have not concerned ourselves with matters
10 that are under jurisdiction dispute. Our task force has
11 had regular meetings for the last several years.

12 On June 28th and October 4th, 1984,
13 representatives of our task force met with representatives
14 of the American College of Radiology, the Society of Nuclear
15 Medicine, and the American College of Nuclear Physicians.
16 At these meetings we had frank and open discussions.
17 Although our position has been that a two- or three-month
18 training period for physicians performing procedures limited
19 to the cardiovascular system is adequate for protection of
20 public safety, we did, at these meetings, agree to a
21 compromise recommendation for a four-month training
22 program. We will accept this compromise training period
23 which we believe is more than adequate to insure public
24 safety in the use of byproduct materials.

25 We're making this statement on the basis of what

1 DAVpp

1 we feel is appropriate for nuclear cardiology and the
2 applications of radioisotopes in the field of nuclear
3 cardiology.

4 ~~As a physician~~ ^{The position} of the American College of
5 Cardiology, the American Heart Association, the American
6 College of Chest Physicians and the American College of
7 Physicians, which represent together over 70,000 physicians, ^{is}
8 that the new NRC requirements of six months of training for
9 physician use of isotopes, especially in those restricted to
10 the practice of nuclear cardiology, is excessive in view of
11 the basic purpose of the NRC activities to ensure safe and
12 knowledgeable handling of clinically radioactive material.

13 We feel that NRC licensure to insure the public
14 health and safety should, in fact, be attainable within a
15 training program of even less than four months.

16 Nevertheless, we have agreed to a compromise with
17 our colleagues and organizations representing the nuclear
18 medicine and the radiology communities. This compromise
19 consists of 650 hours of training with experience in at
20 least 100 documented patients.

21 I must emphasize that this represents a
22 considerable compromise since it has been our position that
23 a 300-hour training period would be adequate to satisfy the
24 NRC's state ^{d intention.} ~~admission~~

25 It is significant that this four-month compromise

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1 training period for licensure of physicians performing
2 radionuclide diagnostic procedures limited to cardiology,
3 has been approved by the American College of Cardiology, the
4 American Heart Association, the American College of
5 Physicians, the American College of Chest Physicians, the
6 American College of Radiology, the Society of Nuclear
7 Medicine, and I believe, the American College of Nuclear
8 Physicians.

9 We've also prepared a detailed description of the
10 200 hours of our proposed training in basic radioisotope
11 handling techniques which I would be prepared to give you
12 after my presentation.

13 It is our position that issues relating to the
14 process of insuring the competence in a clinical practice of
15 medicine should be left in the hands of professional
16 societies, residency and fellowship review groups, and
17 boards and state and hospital accreditation bodies.

18 In summary, Mr. Cunningham, it is the position of
19 the American Heart Association, the American College of
20 Cardiology, the American College of Physicians, the American
21 College of Chest Physicians that a four-month training
22 requirement is a compromise position, but that actually two
23 to three months of training would be more appropriate for
24 carrying out the mission of the NRC.

25 At least for the needs of the practice of nuclear

1 cardiology, we believe that a four-month training period is
2 more than sufficient to meet the Nuclear Regulatory
3 Commission's responsibility to insure public health and
4 safety and to limit licensure to those who use one, two,
5 three and four isotopes in approved form.

6 Thank you for giving me the opportunity to
7 testify.

8 MR. CUNNINGHAM: Thank you very much,
9 Dr. Schlant.

10 Are there any questions by members of the
11 committee?

12 (No response.)

13 MR. CUNNINGHAM: Again, I have a question.

14 You talk about a compromise in training
15 requirements. In other medical organizations, assuming that
16 the people who work on these compromises -- or who
17 participated in these meetings rather -- are all
18 well-qualified people.

19 Why, in your opinion, do you think there is such
20 a diverse opinion as to what is necessary for training to
21 protect the public health and safety on these isotopes.

22 DR. SCHLANT: Some of these, for example, will
23 depend on whether the training was dealing only with safety
24 or also involved areas of clinical competence. In the past
25 some recommendations have been made, for example, that

1 DAVpp

1 involve a total training period that was not just dealing
2 with matters of radiation safety and protection of the
3 public and physicians and everybody and also excessive
4 duplication.

5 But it also involved other areas of clinical
6 experience and knowledge and selection and tests and
7 interpretation of tests, and the sensitivity as to which
8 test to use. So there's an overlap between areas that we
9 would consider more in clinical competence and experience
10 versus those dealing primarily with radiation safety. They
11 do, obviously, overlap but I think that some of it had to
12 with those matters.

13 DR. HOLMAN: I just have one question about the
14 report of the combined group concerning the 650 hour
15 requirement. This is obviously a move from 500 hours of
16 training in isotope handling plus 500 hours of clinical
17 experience. I wonder exactly what you had in mind in terms
18 of structuring that 650 hours so it would meet the needs of
19 both handling and training?

20 DR. SCHLANT: The 650 would roughly be broken
21 down into the initial 200 hours of radiation safety
22 including didactic lectures on radiation physics,
23 radiopharmaceuticals and other subjects. I have a breakdown
24 of that.

25 There will be approximately 250 hours of handling

1 DAVpp

1 of radiation, radionuclide materials. And approximately 200
2 more dealing with at least 100 patient studies and more
3 clinical aspects, in addition, in virtually all programs
4 both in radiology and in cardiology as well as nuclear
5 medicine.

6 The remainder of the program consists of
7 extensive patient contact -- cardiology, certainly, where
8 the trainees are continually exposed to these techniques --
9 interpretation, selection of them, and I think, avoiding
10 excessive duplication both from a cost and a radiation
11 standpoint.

12 But the 650 hours is broken down. We have
13 recommended, by the way, this so-called compromise, 650
14 hours, not the 700 that finally came out in the federal
15 register. It was four months but we allow them a little
16 vacation there, so it actually came out to 650 rather than
17 700 hours.

18 MR. CUNNINGHAM: Thank you very much.

19 The next speaker is Dr. Blahd.

20 DR. BLAHD: Mr. Cunningham, members of the
21 committee. I'm William H. Blahd. I'm at the Wadsworth
22 Veterans Administration Hospital in West Los Angeles and
23 Professor of Medicine at the UCLA School of Medicine.

24 I'm former Chairman of the American Board of
25 Nuclear Medicine; former President of the Society of Nuclear

1 Medicine; and a Regent of the American College of Nuclear
2 Physicians.

3 I'm here today to present the views of the
4 American Board of Nuclear ~~Board of~~ Medicine concerning the
5 petition of the American College of Cardiology to change the
6 training and experience requirements of the Nuclear
7 Regulatory Commission, for ^{physicians} ~~positions~~ who wish to use
8 byproduct materials for the performance of cardiovascular
9 diagnostic procedures.

10 The full statement of the Board has been duly
11 submitted to the Nuclear Regulatory Commission for its
12 consideration. However, the Board wishes to emphasize
13 certain aspects of its statement for the committee's
14 consideration.

15 In 1980 and 1982, the American Board of Nuclear
16 Medicine and other responsible nuclear medicine professional
17 organizations, including the Society of Nuclear Medicine,
18 the American College of Nuclear Physicians, the American
19 College of Nuclear Medicine, the College of American
20 Pathologists, the American College of Radiology, and the
21 American Medical Association, all provided extensive
22 information to the NRC supporting the concept that the
23 minimal requirements for licensure for specific uses of
24 radioactive materials ^{sh} would be increased from 3 to 6 months
25 ^{of} training and experience.

1 Based on these recommendations ^{of} ~~to~~ the nuclear
2 medicine community, the NRC ultimately established six
3 months of training and experience as a minimum requirement
4 for licensure and incorporated these recommendations and
5 regulations. That became effective in July, '84.

6 In December, 1983, as I understand it, the NRC
7 received a petition from the American College of Cardiology
8 requesting that the requirements for licensure for
9 physicians who wish to perform cardiovascular nuclear
10 medicine procedures, be reduced. No evidence was presented
11 to indicate that the carefully considered opinions and
12 deliberations of 1980 and 1982 upon which the NRC's [,] current
13 regulations are based, are no longer valid.

14 Cardiovascular nuclear medicine procedures have
15 become no less complex and, if anything, are more
16 complicated. The safety of medical work errors and patients
17 is even more at risk as a result of the increasing
18 complexity in the use of these procedures. In fact, the
19 Board believes that this six-months training and experience
20 for licensure is the bare minimum time needed to attain
21 competency to perform cardiovascular nuclear medicine
22 procedures.

23 According to the NRC interpretation of
24 professional competency, as expressed in Volume 44 of the
25 Federal Register No. 8242, "The staff ^{has} and will continue to

1 DAVpp

1 interpret this to mean ~~that's competency~~ that NRC approval
2 of a physician to use byproduct materials in humans for
3 treatment and diagnosis relates to radiation safety; to
4 training sufficient to avoid unwarranted radiation exposure
5 to the physician, medical workers and the public, including
6 patients."

7 Since cardiovascular nuclear medicine procedures
8 are some of the most complex, difficult, and demanding
9 nuclear medicine procedures requiring detailed knowledge,
10 not only of the principles of radiological and health
11 physics, but also equally detailed knowledge of methods of
12 radiation detection, image formation and processing, and
13 computer utilization and image interpretation,

14 It follows that the use of these techniques by
15 inadequately trained physicians can result in the
16 performance of test procedures that are not indicated, not
17 properly performed, and incompetently interpreted.

18 Although, the unfortunate consequences of
19 physicians' inadequate training and experience may not result
20 in reportable deaths, they may result in unnecessary staff
21 and patient radiation exposure.

22 The concept that these most difficult nuclear
23 medicine procedures can be mastered in less than six months
24 of intensive training and experience, and that such training
25 can provide a level of competency that will protect the

1 DAVpp

1 public and patients, is patently unrealistic.

2 In view of the extensive body of knowledge that
3 must be acquired to competently practice cardiovascular
4 nuclear medicine, the Board has carefully considered the
5 proposal of the American College of Cardiology to reduce
6 training and experience requirements for licensure⁶ to
7 perform cardiovascular nuclear medicine procedures, and has
8 determined that such changes may be inimical to patient
9 safety and therefore are not in the public interest.

10 Accordingly, the Board urges that the NRC not
11 change its six-months training and experience requirement
12 for licensure for physicians who wish to practice any aspect
13 of nuclear medicine, including cardiovascular nuclear
14 medicine.

15 The American Board of Nuclear Medicine expresses
16 its appreciation for this opportunity to express its views.
17 Thank you.

18 MR. CUNNINGHAM: Thank you very much, Dr. Bland.
19 Any questions by members?

20 DR. POHOST: Dr. Bland, are you aware of the new
21 compromise position that the ~~Science~~^{Society} of Nuclear Medicine and
22 the American College of Radiology and the American College
23 of Cardiology came up with? Is the Board aware of it?

24 DR. BLAND: Yes, indeed.

25 DR. POHOST: In the face of that expert group of

1 DAVpp

1 individuals, do you still propose retaining six-month?

2 DR. BLAHD: That's the Board's position.

3 DR. POHOST: I just want to make it clear. This
4 is not the position shared by your colleagues.5 DR. BLAHD: Of course it's the Board's position.
6 I understand what you're saying.

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1 MR. CUNNINGHAM: I think we'll hear from the
2 Society of Nuclear Medicine later on. I'd have a couple of
3 questions for you.

4 You're quite firm on the minimum six months
5 training requirement. In fact, you feel it should be
6 higher.

7 DR. BLAHD: The Board has always felt that way.

8 MR. CUNNINGHAM: Given the fact that technicians
9 do much of the radioisotope handling in the nuclear medicine
10 laboratory, and what this training relates to is really
11 health physics, ~~How~~ how much training do you think each
12 technician should have relative to the physician to provide
13 safety in handling of radioisotopes?

14 DR. BLAHD: We feel, I guess, that the
15 technicians should be competently trained. Most of them
16 have at least one full year of training.

17 MR. CUNNINGHAM: In radiation safety?

18 DR. BLAHD: That's part of their training.

19 Our technologists in our school receive, I guess,
20 roughly equivalent to 200 hours of training in radiation
21 safety and related basic sciences anyway.

22 MR. CUNNINGHAM: Am I interpreting your answer
23 correctly? I want to be sure of it. Are you saying that
24 technicians should have as much training in radiation safety
25 as the physician and that should be at least six months.

1 DAVpp

1 DR. BLAHD: No, I'm not saying that technicians
2 have to have six months of training in radiation safety.
3 They have to have six months in the aspects that are
4 important. This includes the basic information, the basic
5 sciences, handling, and patient experience. I'm not saying
6 this is all radiation safety.

7 The Board has always considered that
8 interpretation as a very important part of safety in terms
9 of the patient's safety. We consider that to be part of
10 radiation training.

11 MR. CUNNINGHAM: Then the place where the
12 controversy seems to rest -- I gather what you're saying
13 -- is in this gray area where you separate clinical
14 competence from radiation safety training?

15 DR. BLAHD: Yes, I think that's true. We, all of
16 us, felt that interpretation is ^{part}~~an~~ of safety. If the
17 procedure is not interpreted properly, if the test is not
18 recommended when it should be or shouldn't be, these are
19 matters also that certainly are important in terms of
20 safety.

21 MR. CUNNINGHAM: That's an issue the committee
22 has to take up.

23 Any other questions of Dr. Blahd?

24 Dr. Goodrich?

25 DR. GOODRICH: Just to help clarify for this

1 DAVpp

1 committee, my concept of the American Boards, whether it be
2 radiology or nuclear medicine, is that they are constituted
3 in such a way that they are independent, completely
4 autonomous with respect to the peer groups, the other
5 societal agencies that deal with the discipline. And in
6 this fashion they represent, essentially, a Mt. Olympus. It
7 is truly the overseer and the benchmark of standards. Is
8 that correct?

9 DR. BLAHD: I think the Board is as interested in
10 radiation safety as any other organization. I think they
11 have the same concerns for patient safety and public
12 safety.

13 DR. GOODRICH: Dr. Christie, is that a
14 reasonable expression from the Board of Radiology?

15 DR. CHRISTIE: What you just said? Yes, it is.

16 DR. GOODRICH: Thank you very much.

17 MR. CUNNINGHAM: Thank you very much, Doctor.

18 DR. BELLER: Mr. Cunningham, members of the
19 Advisory Committee. My name is Dr. George Beller,
20 representing the American Heart Association. Unfortunately,
21 Dr. Ryan could not be here.

22 I'm Head of the Division of Cardiology and
23 Professor of Medicine at the University of Virginia Medical
24 Center.

25 Since my arrival there in 1977, I have been

1 DAVpp

1 personally responsible for the training of nuclear
2 cardiology fellows in our residency training program in
3 cardiology. I've also been a member of the American Heart
4 Association and the American College of Cardiology combined
5 task force on nuclear cardiology issues.

6 I'm also a member of the Society of Nuclear
7 Medicine and have been involved in the general^{ation of} of multiple
8 documents over the years on training guidelines for nuclear
9 cardiology training.

10 On behalf of the American Heart Association and
11 the American College of Chest Physicians, I would like to
12 declare support for the four-month training period for
13 physicians who only want to perform cardiovascular imaging
14 procedures.

15 There is no doubt that public safety will be
16 assured if this compromise proposal is accepted. We feel
17 that the four-month training program is more than adequate
18 to meet NRC requirements.

19 Now, in most cardiology ~~and~~ training programs,
20 supervised examination of patients to determine suitability
21 for radioisotope diagnosis and recommendation on dosage to
22 be prescribed as well as collaboration in the interpretation
23 of radionucle^{ide} test results, often involves significantly
24 more than the 100 patients as described in the minimum
25 requirements.

Our Fellows are each involved in nearly 900 to 1,000 new nuclear cardiology studies over a two-year period. All case histories are reviewed under the tutelage of an attending nuclear cardiologist or physician.

I believe that the reason for the sentiment in 1980 to increase training requirements ^{to} ~~of~~ six months by my colleagues who testified in a similar advisory committee meeting, is really geared towards increasing the competency in clinical training in radionuclear ^{ide} ~~ide~~ imaging involving more experience in exercise stress testing techniques, scan interpretation, learning more cardiovascular pathophysiology as it related to ^{nuclear} ~~nuclear~~ cardiology testing, hemodynamics and the like.

This was not intended as a recommendation to increase the requirements for training and experience in basic science or radiation safety. Most accredited, let me say, cardiology fellowship training programs' trainees undergo an extensive ^P ~~exposure~~ exposure to the decision-making process of which radionuclear ^{ide} ~~ide~~ test is appropriate, if any. What are the advantages and disadvantages of a particular nuclear cardiology test?

They're also trained throughout their period of fellowship ^{as} ~~to~~ the manner in which optimum performance of tests, or optimum quality results, are achieved. They are supervised in scan interpretation on daily reading sessions

1 and weekly or biweekly conferences.

2 Correlation with other tests such as cardiac
3 catheterization, echo cardiography, is an important part of
4 the training, in order to better understand the
5 false-positive or false-negative results that are often
6 acquired or occasionally acquired and follow-up of patients
7 is also part of the standard nuclear cardiology training
8 program.

9 So therefore, although the requirements of the
10 four-month training period are sufficient, we believe, for
11 licensure for nuclear cardiology practice, the exposure to
12 nuclear cardiology clinical procedures goes on for the
13 entire program on a patient-by-patient basis.

14 Therefore, we believe, clinical competency is a
15 continuum which involves multiple rotations throughout the
16 training program.

17 Thank you.

18 MR. CUNNINGHAM: Thank you very much, Dr. Beller.

19 Are there any questions of Dr. Beller?

20 Yes, Dr. Workman?

21 DR. WORKMAN: Perhaps I missed this. I apologize
22 if I did.

23 Did you mention the basic training? You spent a
24 good bit of time on the clinical training but how many hours
25 of basic training do you people at UVa get?

1 DR. BELLER: The number is close to, I believe,
2 well over, I think, 600 hours. This is done where our
3 cardiology trainees go to the nuclear medicine service in
4 July at the beginning of a year and undergo this basic
5 training, didactic lectures, radioisotope handling with the
6 radiology residents. Then they come back to the cardiology
7 fellowship program and, over the subsequent two years, we
8 believe that it is very important for them to become expert
9 in the clinical interpretation of scans because -- as was
10 mentioned previously by another speaker -- this involves
11 patient safety as well to minimize false-positive
12 interpretations which then may lead to unnecessary invasive
13 procedures.

14 MR. CUNNINGHAM: Thank you very much, Dr. Beller.
15 Dr. Siegel?

16 DR. SIEGEL: Mr. Cunningham, members of the
17 Advisory Committee.

18 My name is Barry Siegel, Professor of Radiology
19 and Medicine and Director of the Division of Nuclear
20 Medicine at Washington University School of Medicine.

21 I also am a Fellow of the American College of
22 Cardiology, Fellow and Government Relations Committee member
23 of the American College of Nuclear Physicians, a Fellow of
24 the American College of Radiology, and Vice Chairman of its
25 Commission on Nuclear Medicine, ~~✓~~ Trustee and Government

1 DAVpp

1 Relations Committee Member of the Society of Nuclear
2 Medicine and an American Board of Radiology Delegate to the
3 American Board of Nuclear Medicine. And a recently retired
4 member of the Residency Review Committee for Nuclear
5 Medicine.

6 I tell you this only as a means of highlighting
7 my multi-organizational perspective on the problem before
8 this committee because today I am representing none of these
9 organizations but rather I'm here to share my personal
10 observations and opinions with the Advisory Committee.

11 The detailed comments in my letter of March 4
12 have already been made available for your review.
13 Accordingly, I wish only to reiterate a few key points.

14 First, I have been concerned for some time now
15 that the lobbying that has led to the augmentation of the
16 minimum training and experience criteria for physician use
17 of byproduct material has been motivated less by a desire to
18 insure radiation safety and more by a desire of certain
19 groups of practitioners to maintain their
20 government-sponsored franchise.

21 In particular, I am puzzled by any professional
22 organization that should wish to increase the intrusion of
23 the federal government, or any government for that matter,
24 into the practice of medicine, especially since the evidence
25 that nuclear medicine is intrinsically unsafe, is not at all

1 DAVpp

1 clear, and since medicine as a whole and nuclear medicine in
2 particular already are regulated to an excessive degree.

3 Despite what I just said, I also firmly believe
4 that more nuclear medicine training is better than less. I
5 also personally believe that it is difficult to train a
6 physician to be an excellent practitioner in our specialty
7 in less than one year; two years is even better in this
8 regard. Therefore, I believe it is quite important to
9 distinguish between the minimum training necessary to insure
10 safe radiation practices and the training necessary to
11 insure that nuclear medicine is practiced to the highest
12 standards of excellence.

13 It is my understanding that the NRC has a
14 statutory mandate to insure safe medical use of byproduct
15 material but does not wish to be responsible for insuring
16 clinical competence.

17 I think this is entirely appropriate since no
18 other medical specialty has federal licensing requirements
19 relating to clinical competence including the several
20 specialties whose practitioners use other forms of ionizing
21 radiation in their medical activities.

22 In all of the rest of medicine, the traditional
23 approach for a delineation of privileges is based on
24 recommendation and the guidelines established by
25 professional societies; the certification process by

1 DAVpp

1 specialty boards of individuals who are trained in formal
2 programs approved by residency review committees; and
3 through the credentialing process of hospital staff
4 accreditation committees.

5 Certainly, poorly trained physicians in other
6 specialties are no less hazardous to the public health and
7 safety than are poorly trained authorized users of byproduct
8 material and, yet, nuclear physicians are subject to a
9 unique additional level of regulation.

10 My objections to the current training and
11 experience criteria to which the monster we have created,
12 are discussed in my letter in some detail.

13 However, it is clear to me, just briefly as a
14 training program director, that a full 500 hours of hands-on
15 experience working with byproduct material is not optimal
16 use of the precious time allotted to the training of
17 residents.

18 Moreover, the 200-hour block of didactic training,
19 albeit time-honored, does not seem to me to be clearly based
20 on any data showing that it takes precisely this long to
21 achieve the educational objectives of such training.

22 Accordingly, I would argue the following: That
23 the NRC should dis-insert itself from the practice of
24 medicine to the fullest extent it believes consistent with
25 its statutory mandate.

1 Whatever training is required should be kept to a
2 minimum; should be based on carefully thought-out and
3 documented objectives; and should be uniformly applied to
4 all applicants for licensure.

5 The process of insuring competence among nuclear
6 medicine practitioners should be left in the hands of those
7 professional bodies that somehow manage to insure competence
8 most of the time in all other medical specialties.

9 To go even one step further, I would suggest that
10 specific physician licensure only should be required for
11 byproduct material use in practice centers where the license
12 is actually granted to a particular physician. In
13 institutional settings where the license is granted to
14 the institution and requires a formal radiation safety
15 program, I believe that the institution should determine who
16 can and cannot be an authorized user.

17 I believe that licensed institutions will be
18 motivated to select the most clinically competent,
19 best-trained individuals as the surest way of guaranteeing
20 that the institution fulfills all of the safety requirements
21 of 10 CFR necessary to gain and maintain licensure.

22 I thank you for the opportunity to address the
23 committee.

24 MR. CUNNINGHAM: Thank you very much, indeed, for
25 your comments, Dr. Siegel.

1 DAVpp

1 Do the committee members have questions of
2 Dr. Siegel?

3 (No response.)

4 MR. CUNNINGHAM: I'm surprised.

5 (Laughter.)

6 MR. CUNNINGHAM: There are two areas, I guess.

7 Your introductory comments that perhaps the real issue
8 behind this question on training is not protection of public
9 health and safety but may be one of economics.

10 Some people have held that suspicion. Is that
11 what you indicated in the first part?

12 DR. SIEGEL: I believe that my involvement in
13 discussions in many different organizations lead me to
14 believe that there may be some truth to that.

15 MR. CUNNINGHAM: That might be part of the
16 issue.

17 DR. SIEGEL: That might at least be part of it.

18 MR. CUNNINGHAM: One other question.

19 You heard Dr. Bland's testimony previously prior
20 to your testimony. We will continue to have problems with
21 this gray area where we begin to separate clinical practice
22 from radiation detection. Do you have any thoughts on that?
23 I recognize your idea of licensing the hospital rather than
24 the physician, but can you help any in making that
25 separation?

1 DR. SIEGEL: I'm not sure that I can really
2 clarify the matter, but I think it really has become the
3 crux of what is dividing opinions here.

4 But I would only suggest that if we really think
5 that the NRC should get into the business of going the full
6 step to insure clinical competence, let's all march downtown
7 as soon as this meeting is over and go to Capitol Hill and
8 HHS and let's get a set of regulations up that are
9 equivalent for diagnostic radiology, for surgery, for
10 medicine, because their kinds of individuals, bad
11 radiologists, bad surgeons, bad internists, are just as
12 dangerous to the public health and safety as ^{are} ~~our~~ bad nuclear
13 medicine physicians.

14 It's pretty hard to do a lot of damage with
15 technetium 99 M. It isn't tough to do damage with a scalpel
16 that doesn't know where it's going.

17 I think we've just blown all this out of
18 proportion.

19 MR. CUNNINGHAM: Thank you very much.

20 Dr. Gould?

21 DR. GOULD: Thank you.

22 I'm Dr. Lance Gould. I want to thank you for
23 being here and ⁱcomplement the NRC Staff for the
24 professionalism and objectivity and fairness -- their
25 professionalism, et cetera. I respect that very much.

1 I'd like to outline my credentials as a basis for
2 my opinion, which would be very brief.

3 I was originally trained in physics and internal
4 medicine and cardiology. Currently, I'm Director of the
5 Division of Cardiology at the University of Texas at Dallas
6 and also the Positron Diagnostic and Research Center,
7 which in perhaps Texas style, may be one of the world's
8 largest positron programs for clinical imaging right now.
9 We have an entire building devoted to this, three cameras
10 ~~en route~~ ^{in routine use,} and the entire staff of physicists, electrical
11 engineers, computer scientists, radio chemists,
12 physiologists, clinical people, and radiologists,
13 neurologists, and psychiatrists, all under one administrative
14 group getting along quite happily.

15 Occasionally, Indians circle this compound in
16 Texas but we manage to survive without Turkey shoes -- ^{shoots(?)} and I
17 want to emphasize that.

18 I represent the AHA and the ACC. I'm also a
19 member of the American Association of Physicians and the
20 American Society for Clinical Investigations sometimes,
21 perhaps, too elitist a group of scientists who have
22 contributed to a variety of medical research.

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1 I would simply like to say that based on my
2 experience and extensive training in developing programs,
3 that I think that the six-month rule is really quite
4 excessive and unnecessary. The three months of training is
5 quite adequate for radiation safety matters.

6 I would like to address your question about why
7 there is this difference of opinion.

8 I, too, believe that it relates to the question
9 of clinical competence and believe that that should be
10 restricted to professional societies and not the
11 responsibility of the NRC.

12 The greatest problems of safety that we have had
13 are the death of a patient who was put on the nuclear study
14 treadmill because the nuclear physician at the time looked
15 at the EKG and did not recognize an acute myocardial
16 infarction in evolution.

17 The second case was a near-death resulting from
18 neurologic deficit permanently in the patient who had
19 complete heart block, also en-route to an EKG. That was not
20 recognized.

21 Those are the sorts of risks that we face that
22 are major ones which required clinical competence and I
23 believe that should be left to the professional societies.

24 It does require extensive training and that the
25 radiation safety matters can be dealt with very well within

1 DAVpp

1 the three-month period. And I would support that point of
2 view.

3 Thank you very much.

4 MR. CUNNINGHAM: Thank you, Dr. Gould.

5 Questions by members of the committee?

6 (No response.)

7 MR. CUNNINGHAM: Thank you very much, Dr. Gould.

8 Dr. Lindgren?

9 DR. LINDGREN: Thank you.

10 My name is Dr. Keith M. Lindgren. I'm a
11 practicing, board-certified cardiologist. In this locale,
12 I'm co-Director of Cardiology at the Washington Adventist
13 Hospital, past President of the Montgomery County Heart
14 Association, Clinical Assistant Professor of Medicine at
15 Georgetown University Medical Center, and Fellow of the
16 American College of Cardiology.

17 I come to you because I am concerned that nuclear
18 cardiology tests must be available in the community where
19 they are crucial to the detection and treatment of heart
20 disease.

21 In the past five years, I've been actively
22 involved both in a hospital setting and working in
23 conjunction with other nuclear medicine professionals, also
24 with colleagues who have often faced ^{hostilities(?)} facilities.

25 With all these nuclear cardiology programs where

1 cardiologists have nuclear medicine training in three months
2 or less, I have never seen or heard of a significant spill
3 accident or safety violation.

4 Furthermore, I understand from my colleagues
5 across the country, that there has never been such an
6 accident involving a nuclear cardiologist in the entire
7 country, a record beyond reproach for training programs that
8 are less than those proposed.

9 Secondly, in reviewing the proposal, it is my
10 experience that with 200 hours of didactic training, an
11 additional 250 hours of handling experience is excessive.
12 This is really part of one's ongoing work in the area.

13 Certainly a training program provides habits for
14 compulsive recordkeeping and meticulous techniques are very
15 important, but it really is the development of this as a
16 lifelong habit rather than specifying in a few months or
17 training a number of hours. And that really requires
18 supervision while you are learning those habits and
19 correction of deficiencies in setting a pattern and then
20 carrying it on for years rather than a matter of a few
21 months.

22 Lastly, I'm concerned about the availability of
23 physicians competent to perform nuclear cardiology tests.

24 As has been pointed out by Dr. Gould and
25 Dr. Beller, the major risk of these tests in cardiology

1 DAVpp

1 involves who should be tested safely taking people with
2 heart disease and running them through exercise tests and
3 similar things. Nuclear cardiology aspects are very crucial
4 but probably not the life threatening or most important
5 clinical matter.

6 As a board-certified cardiologist with 15 years
7 of experience and knowledge of cardiac pathophysiology --
8 which is really the basis of the way the nuclear medicine
9 test gives us information -- cardiac catheterization
10 techniques with experience in radiation imaging and
11 interpretation, long experience with exercise testing,
12 advanced cardiac life support to be able to take care of
13 problems should they develop in the laboratory. All of this
14 is necessary to competently and safely do and interpret^P_K
15 nuclear cardiology tests.

16 I was able to learn the nuclear medicine theory
17 and practice of safety in an efficient course. If you had
18 to similarly train a current medical school graduate, take
19 him and train him to the level of clinical cardiology
20 competence necessary to decide who should have the test,
21 conduct the test properly, make sure it's done safely and
22 interpret the test accurately, the nuclear medicine safety
23 aspects of it are really a very minor part.

24 The major costs and importance of training is
25 really the clinical competence and that has been pointed out

1 DAVpp

1 by many people.

2 I think what past experience has done has shown
3 that nuclear medicine training programs that include
4 radiation safety procedures of less than four months, have
5 done that job. The safety record of nuclear cardiologists
6 demonstrate that nuclear medicine training for cardiologists
7 need not be lengthy.

8 I appreciate your allowing me to express my views
9 before your group.

10 MR. CUNNINGHAM: Thank you very much,
11 Dr. Lindgren.

12 Dr. Holman?

13 DR. HOLMAN: I'm sorry; I may have missed it.
14 What are you proposing to us that we do?

15 DR. LINDGREN: My basic purpose is to say that I
16 think there's no need to lengthen the training program in
17 nuclear medicine as it pertains to nuclear cardiology.

18 I think the past record does not demonstrate any
19 need.

20 DR. HOLMAN: So you are suggesting the four-month
21 compromise?

22 DR. LINDGREN: It is certainly long enough; yes.

23 MR. CUNNINGHAM: Mr. McElroy?

24 MR. MC ELROY: Could you characterize for the NRC
25 Staff's benefit the approval mechanism that a hospital uses

1 DAVpp

1 when granting privileges to a doctor in any department?

2 DR. LINDGREN: Actually, I'm sure that varies
3 from hospital to hospital. I would speak only of the
4 cardiologists in our hospital. They're covered by the
5 license of the hospital nuclear medicine department. Only
6 two of us have nuclear medicine licensures so that our
7 cardiologists doing the clinical cardiology part of it, and
8 the tests are interpreted jointly by the nuclear medicine
9 people and radiology.

10 So we have worked out a joint combination but
11 that varies across the country.

12 MR. MC ELROY: No, I mean to ask for other
13 medical specialists such as surgeons?

14 DR. LINDGREN: I'm not sure any other group of
15 subspecialists in our hospital really does nuclear medicine
16 testing.

17 MR. MC ELROY: My question, then, isn't clear.

18 Does the hospital have some approval mechanism
19 before it lets a doctor come in ^{to} practice, whatever specialty
20 he practices; not just nuclear?

21 DR. LINDGREN: Certainly, right.

22 MR. MC ELROY: Can you explain that approval
23 mechanism?

24 DR. LINDGREN: This is a medical staff
25 procedure. You have to have at least certification or board

1 DAVpp

1 qualification or a subspecialty. Your credentials have to
2 be reviewed. All of this has to be documented and approved
3 not only by the credential's committee of the hospital, but
4 also by the department in which that subspecialty falls. So
5 you have to have training documented by board certification
6 and qualification. If not, he must go through a training
7 program adequate to meet the board qualification.

8 MR. MC ELROY: Does the Joint Commission on
9 Accreditation of Hospitals review this paper path?

10 DR. LINDGREN: Yes.

11 DR. WOODBURY: You ~~would~~^{have} only board certifi^{ied}
12 physicians on your medical staff?

13 DR. LINDGREN: No. But to achieve certain
14 privileges, for example, to do cardiac catheterization in
15 our hospital, yes, you have to be board certified.

16 DR. WOODBURY: I was just a little curious about
17 the curious -- the implication of the question is that
18 medical practice is primarily in hospitals. I'd like to
19 remind the Staff that there is a good deal of medical
20 practice outside of hospitals with entirely different sets
21 of credentials.

22 DR. WEBSTER: You seem to have uncovered a
23 Pandora's box that I didn't intend to open but what does the
24 Board of Cardiology have to say about examination of
25 cardiologists in the nuclear medicine area -- nuclear

1 DAVpp

1 cardiology -- do they do it?

2 DR. LINDGREN: I think most cardiology training
3 programs that would graduate a subspecialist would certify
4 that he is adequately trained in that area. That has to do
5 with other areas within cardiology such as catheterization
6 and echo cardiography. All those techniques are learned in
7 one's training program and one's training program verifies
8 adequate training.

9 Certainly, in cardiac catheterization probably we
10 examine more thoroughly than, say, nuclear medicine
11 training. We have to have documentation from their mentor
12 of the number of cases that they have done and their record
13 so we do look at that as a credentialing body.

14 In other areas, we have not done that.

15 DR. WEBSTER: The gist of my question is that the
16 cardiologist would probably tend to rely more on licensure
17 by the NRC than board certification because it would
18 emphasize -- I think is what I'm hearing from you -- the
19 nuclear medicine component much more strongly; is that true?

20 DR. LINDGREN: I think that if a person -- a
21 cardiologist wants to use nuclear medicine, say, outside of
22 a hospital setting where there's a radiation safety officer
23 and such, certainly, he has to be licensed.

24 And once again, that's not a hospital looking at
25 his credentials. We, in viewing people who do nuclear

1 medicine testing within the hospital, rely on the training
2 program to verify their qualifications to do and interpret
3 nuclear medicine tests.

4 MR. CUNNINGHAM: Captain Briner?

5 CAPT. BRINER: Currently, what are those
6 qualifications you look at? I'm not clear on that.

7 DR. LINDGREN: They are the training program --
8 in other words, we'll state that they are qualified to do
9 and interpret, and usually recite the number of kind of
10 tests they can do, thallium exercise tests if they have
11 received adequate training in both supervising and deciding
12 upon the implications for interpreting these tests.

13 CAPT. BRINER: Who decides whether the training
14 is adequate in that area?

15 DR. LINDGREN: Their training program.

16 DR. WORKMAN: The American College of Cardiology
17 does not examine applicants, then, in radionuclide studies?

18 DR. LINDGREN: I think that is the job of the
19 certifying body. There is board certification in
20 cardiovascular diseases which are certifying bodies.

21 DR. WORKMAN: Do they examine people?

22 DR. LINDGREN: They cover the whole spectrum,
23 yes. I can't quote chapter and verse about how much
24 radiation safety is on that examination.

25 MR. CUNNINGHAM: I want to be real clear on this

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1 to be sure I understand it.

2 In board certification in cardiology, they test
3 and recognize a certain level of competence in nuclear
4 cardiovascular diagnostic procedures; is that correct?

5 DR. LINDGREN: That is part of the training
6 program and, as I said, I haven't taken the board's
7 recently, but I think that in covering the broad spectrum of
8 cardiology training, they would cover the application and
9 use of nuclear medicine.

10 MR. CUNNINGHAM: It's part of the determination
11 of --

12 DR. LINDGREN: Board certification.

13 MR. CUNNINGHAM: Perhaps if you'd be so kind as
14 to supplement the record on that.

15 DR. LINDGREN: Okay. I'll have to be in contact
16 with ~~you~~ of the American Board of Internal Medicine, which
17 is the governing body. *

18 MR. CUNNINGHAM: Any other questions?

19 Dr. Goodrich?

20 DR. GOODRICH: Of your own personal knowledge of
21 the training programs that you've participated in and
22 others in your peer group, have you ever known anyone who
23 was not approved or who was required to take additional
24 training in order to satisfy the basic concerns of this
25 body?

* In letter dated 5/24/85 Dr Lindgren said, "The exam of the ABIM for cardiovascular disease contains questions dealing with nuclear cardiology including radionuclide ventriculography and exercise thallium testing, coronary arteriography, cardiac catheterization and angiography."

1 DR. LINDGREN: In nuclear cardiology? No, I
2 don't know of any one individual who was asked to return and
3 get more training; no.

4 MR. CUNNINGHAM: Thank you.

5 ~~Dr. Miller?~~
~~POHST?~~

6 DR. ~~MILLER~~ ~~POHST~~: How many of your trainees are
7 certified in nuclear cardiology?

8 DR. LINDGREN: Now, we're a group of five
9 hospital-based cardiologists. All five do nuclear medicine
10 testing. Only two of us are licensed.

11 ~~POHST:~~
~~DR. MILLER~~: Do you have a training program?

12 DR. LINDGREN: No. We rely entirely on their
13 training programs before they join us.

14 MR. CUNNINGHAM: Thank you very much.

15 Dr. Goldberg?

16 DR. GOLDBERG: I'm Daniel J. Goldberg. I'm a
17 board-certified cardiologist in private practice in
18 Bethesda, Maryland. I'm a Fellow of the American College of
19 Cardiology.

20 My practice has a special interest in the area of
21 nuclear cardiology and, as well, I have to obtain a license
22 to practice nuclear cardiology in this state. After
23 studying the current NRC regulations for licensure, I
24 believe they have a significant shortcoming.

25 Primarily, they fail to recognize the exposure to

1 radiation safety that physicians require during the course
2 of their entire training.

3 Physician's training in radiation safety begins
4 as a medical student. Exposure to radiation-related
5 subjects, including radiation safety, is continued
6 throughout the internal medicine internship and residency.

7 When the physician decides to become a
8 cardiologist, he enters into approved cardiology fellowship
9 training, as we all know. He must master tremendous skills
10 within two or three years. These include many diagnostic
11 skills, including electrocardiography, electrophysiology,
12 stress testing, cardiac catheterization, expertise in
13 hemodynamics, and obviously, nuclear cardiology.

14 I feel they are all complimentary. They allow
15 the cardiologist to ^{perform}~~form~~ each one of his techniques more
16 expertly. Specifically, training in a cardiac
17 catheterization laboratory includes extensive experience in
18 the concepts of radiation exposure, radiation protection and
19 especially radiation safety.

20 This is supported by the documentation over the
21 past decade of hundreds of thousands of angiographic
22 procedures that have been performed by cardiologists without
23 any reports of a radiation-related safety event.

24 Therefore, when this physician moves into the
25 arena of nuclear cardiology, he brings with him a heightened

1 awareness or concern for radiation safety that has already
2 been inculcated in him in the cardiac catheterization
3 laboratory.

4 Personally, I have worked in six different
5 nuclear laboratories in six years. Four of them were
6 supervised by nuclear cardiologists. These experiences
7 occurred during my fellowship and since I've been in private
8 practice. They occurred in the State of Kentucky and the
9 State of Maryland.

10 During this time I have not seen any adverse
11 patient event due to inadequate safety precautions,
12 especially in the laboratory supervised by the nuclear
13 cardiologist.

14 During my cardiology training, I experienced the
15 kind of training which was presently recommended and
16 presently is held by the NRC. I have 500 hours of
17 supervised experience in the handling of radioactive
18 materials, in addition to 250 hours of didactics.

19 My experience -- we were not forced but we were
20 asked to at least be involved in at least 600 hours of
21 clinical experience, which was totally separate and often
22 run concurrently with the other part of the training.

23 Certain questions were asked ^{of} ~~to~~ Dr. Lindgren
24 regarding certification in a cardiology fellowship program.
25 Since I finished my fellowship five years ago -- four

1 years ago to be exact -- the question was asked was anyone
2 ever not certified to do nuclear cardiology. I can say
3 yes.

4 In the training program that I was in, there were
5 approximately eight to ten people. Only four of the eight
6 were allowed to apply for their license at that time. This
7 decision was made by a radiation physicist, by the director
8 of the nuclear medicine program, and by the director of
9 cardiology.

10 So there have been people who, in my opinion,
11 have not been accepted to be approved by the program. I
12 believe that the amount of experience that I received was
13 excessive and overkill. I felt that it was excessive in
14 terms of handling ^{and} the principles of radiation safety.

15 It's for this reason that I feel that the
16 licensure criteria could be easily met over the three to
17 four months.

18 I firmly believe that it is necessary for
19 guidelines to be established delineating the amount of
20 training necessary to safely handle the use of radioactive
21 isotopes. This training must include didactics, supervised
22 clinical experience, and expertise in the handling of sealed
23 and unsealed radioactive isotopes.

24 However, in my opinion, the present NRC ruling is
25 excessive in that it does not take into account overall

1 DAVpp

1 training and experience that the physician in the cardiology
2 fellowship receives.

3 I, therefore, support the recommendation proposed
4 by the American College of Cardiology and the American Heart
5 Association. I feel they recognize the total training of
6 the cardiologist and the present training program at this
7 time.

8 Thank you for granting me this time.

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1 MR. CUNNINGHAM: Thank you very much,
2 Dr. Goldberg.

3 Questions?

4 Dr. DeNardo?

5 DR. DE NARDO: Did you do the studies you were
6 talking about in your office?

7 DR. GOLDBERG: No.

8 DR. DE NARDO: Thank you.

9 MR. CUNNINGHAM: Any other questions?
10 (No response.)

11 MR. CUNNINGHAM: Thank you.

12 Dr. Ronan?

13 DR. RONAN: Mr. Cunningham, member^S of the
14 Advisory Committee, thank you for allowing me to express my
15 opinion on these matters.

16 My name is James Ronan, a cardiologist in private
17 practice of cardiology in this community.

18 I'm interested in the area of nuclear cardiology
19 and I've been licensed by the NRC to handle radioactive
20 materials in cardiovascular diagnostic procedures.

21 I'm also interested in the training of physicians
22 in cardiology and I previously served for nine years as
23 full-time faculty in the Department of Cardiology of
24 Georgetown University School of Medicine.

25 I still teach weekly and hold the rank of

1 DAVpp

1 Clinical Professor of Medicine at that institution.

2 I mention this background only to indicate my
3 interest and experience in teaching and learning because I
4 believe that the NRC is establishing the required curriculum
5 for education and handling radioactive materials.

6 Radiation safety is the goal of that curriculum
7 and like many scientific courses, has been divided into
8 sections of lectures and two separate sections of practical
9 application unrelated to basic radionuclide handling
10 techniques and one to clinical training.

11 While the subject matter included in this
12 curriculum is reasonable, it appears that the decisions made
13 as to the time required to accomplish those goals, although
14 possible, are somewhat arbitrary.

15 The background biology and mathematics in
16 radiation protection cannot be argued. That knowledge is
17 absolutely mandatory.

18 The requirement for 200 hours worth of didactic
19 work in those fields may seem excessive to some and is
20 really the equivalent of 12 semester college credit hours.
21 But in my judgment, it's not unreasonable.

22 However, the weakness in the logic of the
23 training requirements, to me, seems to lie in the second
24 part of the program and in our failure to recognize the
25 overlap and the knowledge transfer which exists between

1 DAVpp

1 these separate areas.

2 In the section devoted to radionuclide handling
3 which is 500 hours, that's equivalent to 62 work days, or
4 three months, that's required. That duration seems
5 particularly excessive when we consider that the subject
6 material which is to be included in that three-month period
7 and let me list that for you:

8 Number one, ordering, receiving and unpackaging
9 radioactive material safely. Number two, calibration of
10 dose calibrators and operational checks on survey meters.
11 Number three, calculation, preparation and calibration of
12 patient doses. Number four, administration of doses to
13 patients. Number five, appropriate internal control
14 procedures to prevent the misadministration of materials to
15 patients. Number six, procedures to handle spilled
16 materials safely and, number seven, ^{elution} illution of technetium
17 99 M from generator systems.

18 These tasks are unquestionably important for
19 sheer safety but they're really not terribly difficult to
20 learn, particularly considering that there are several
21 overlaps between the original 200 hours and the 500 hours,
22 dedicated to handling the material. The foundation for all
23 those tasks will have already been covered in great detail
24 in the didactic portion and that knowledge is directly
25 transferable.

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1 Furthermore, many of the tasks in the group are
2 simply bookkeeping and recordkeeping chores having to do
3 with ordering, receiving, and preventing the
4 misadministration of materials. It really should not take
5 three months to learn those tasks, particularly when the
6 physician has the basic scientific background and 200 hours
7 worth of preparation.

8 I recently asked a technician in our nuclear
9 medicine department how long he thought it would take to
10 teach a technician those tasks, granted that they already
11 have their own background, their material. Their estimates
12 ranged from one to two weeks. That is, from 40 to 80
13 hours. Certainly, it should not take most physicians three
14 months.

15 I understand the importance of this experience
16 and I don't mean to minimize it. I just think that the
17 arbitrary decision to require 500 hours in this curriculum
18 is just not reasonable, and it's prolonging the program
19 unnecessarily.

20 Lastly, let me say that the separation of the
21 500 hours in handling from the 500 hours required for
22 clinical training, is an artificial separation and is really
23 not realistic. There's considerable overlap in knowledge
24 transfer between those portions of the curriculum and it's
25 probable that a trainee would and should consider them

2 DAVpp

1 together.

2 Ideally, a trainee should be totally involved in
3 the patient's problem so that during this period of
4 training, he could examine the patient and select the
5 appropriate nuclear test, order the radionuclide, calculate,
6 prepare or calibrate, and administer the dose and also
7 interpret the test. That's a logical way to train a
8 person.

9 Separating those tasks into two different
10 categories is an artificial separation. Let me say that I
11 don't know the correct answer to the time required for this
12 curriculum. My division may be just as arbitrary as others,
13 however, I think we must recognize that there's a great deal
14 of overlap between the subject materials and the tasks
15 considered in these three separate categories, and that we
16 should not consider them as entirely separate, independent
17 courses needed to graduate.

18 The last two categories have been separated
19 mainly because we're accustomed to thinking of them as
20 separate individual responsibilities. Those tasks in the
21 handling category are placed in the hands of the
22 technician traditionally, while those in the clinical area
23 have been the physician's responsibility.

24 Well, different tasks have been in practice
25 before by different persons. There's no reason why, in that

1 DAVpp

1 period of training, they could not be learned
2 simultaneously, thereby, reducing the required time for
3 learning.

4 Some comparison could be made to the curriculum
5 in an automobile driving school. A certain number of hours
6 is not devoted exclusively to learning to stop the car while
7 another certain number of hours is not devoted exclusively
8 to learning to turn the car.

9 There's considerable overlap in the process of
10 learning those skills. It's my estimate that the 200-hour
11 didactic material will be retained, but that the remaining
12 material can be learned in three months.

13 Furthermore, the clinical period of training
14 would only be the starting time for the cardiologist in that
15 three-month period. That's only the beginning of their
16 experience. They will necessarily continue to learn
17 throughout their clinical experience.

18 Thank you very much.

19 MR. CUNNINGHAM: Thank you very much.

20 Questions?

21 DR. GRIEM: Where is the basic math and physics
22 in this program, the concept of tissue absorption and all
23 these things.

24 DR. RONAN: It's a very extensive program. In
25 the course I took, we had 200 hours. It seemed like it was

1 eternal for me. It seems like it never ended. It's the
2 equivalent of 12 college credit semester hours. A lot of
3 time, and I don't think we need to relearn that when we
4 go in the laboratory to write out the procedure for the
5 radioisotopes.

6 MR. CUNNINGHAM: Dr. DeNardo?

7 DR. DE NARDO: Are you doing any single photon
8 ~~emission?~~
~~emerging?~~

9 DR. RONAN: No.

10 DR. DE NARDO: Do you intend to?

11 DR. RONAN: I can't answer that.

12 DR. DE NARDO: If you were to do so, how would
13 you set up the quality control for the instrumentations?

14 DR. RONAN: I wouldn't want to do it until I went
15 through training and felt qualified to do that.

16 DR. DE NARDO: Thank you.

17 MR. CUNNINGHAM: Thank you very much.

18 It's now 10:30. I'd hoped we'd be through with
19 these presentations but I've had questions as have members
20 of the committee.

21 Perhaps we should take no more than a 15-minute
22 break and be back here.

23 (Recess.)

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MR. CUNNINGHAM: We've got to start again.

The next person that wants to make a statement is Dr. Lindsay.

DR. LINDSAY: Mr. Chairman and committee members, I'm Dr. Joe Lindsay. I'm an academic Cardiologist and I've been a faculty member of three medical schools for 19 years. In my practice I've been interested primarily in patient care -- I've been a clinician -- and the teaching of patient care. I'm presently a program director of a fellowship program in cardiology.

I came to nuclear cardiology somewhat late in my career, in 1976, attracted by the advantages this technique seemed to offer my patients. And through a very cooperative team effort with the Nuclear Medicine Department in our institution, I have been heavily involved in it now for that seven-year period to the point that I have been a principal author of about five papers in referee journals relating to clinical application of these techniques.

I have been impressed primarily by the very favorable impact of nuclear cardiology on the care of my patients. I'll mention only one of the numerous favorable impacts that exist. That is the ability to select more carefully patients to undergo cardiac catheterization, a procedure which, as you know, carries some small risk to the patient in addition to a substantial radiation exposure to

1 DAVpp

1 the patient as well as to the physician doing the
2 examination.

3 I support the position of the American College of
4 Cardiology and the compromise proposal for a four-month
5 training period because, while I believe that the ideal
6 approach to nuclear cardiology is a team effort between a
7 nuclear medicine physician or a radiologist and a
8 cardiologist, this approach is often impossible,
9 particularly in smaller centers and particularly in
10 outpatient settings.

11 The increased training from three to six months
12 has resulted in a reduced number of cardiologists who can be
13 qualified to offer these services to our patients, thus,
14 certain patients may be deprived of the opportunity to have
15 these important diagnostic tools. This should not take
16 place, in my view, because of an inappropriately long
17 required training period.

18 In addition, as has been pointed out before,
19 to any period devoted exclusively to nuclear cardiology,
20 cardiology training incorporates a supervised training and
21 integration of nuclear cardiology findings to the care of
22 the patient.

23 I fully understand and heartily support the
24 concern of the Nuclear Regulatory Commission in the handling
25 of isotopes. I would have it no other way. But I would

1 DAVpp

1 urge you to make your decision on the basis of the grounds
2 of safety, taking into account the excellent safety record
3 that has been produced by nuclear cardiologists testing as
4 well as the limited number of tests and isotopes to be
5 employed by cardiologists authorized to use these.

6 Thank you for allowing me to testify.

7 MR. CUNNINGHAM: Thank you very much,

8 Dr. Lindsay.

9 Any questions by members of the committee?

10 (No response.)

11 MR. CUNNINGHAM: I see no questions. Thank you
12 very much.

13 Dr. Fox?

14 DR. FOX: Mr. Chairman, ladies and gentlemen.

15 I'm Dr. ^{Lay}~~Larry~~ Fox. I'm a practicing
16 cardiologist. After spending 21 years in the Navy, when I
17 retired I joined the faculty of Georgetown University. I've
18 been practicing cardiology at Georgetown since then. For
19 the last five years I've been doing nuclear cardiology in
20 the Nuclear Medicine Department at Georgetown.

21 I recently, through my own interest, went and
22 took the five-week course of didactic training in a program
23 designed to meet the NRC requirements. I didn't do it
24 because I needed the certification because I was practicing
25 in a nuclear medicine setting and I found no need for that.

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1 But I did it out of my own interest.

2 I found it quite interesting and enjoyable. I
3 did find that at least half -- or I'll say a significant
4 portion of the time -- was spent on subjects and modalities
5 that had very little relationship to cardiology.

6 For instance, radioimmunoassay is something that
7 I have no plans to use personally, that is, to employ these
8 procedures myself. ^{Also} ~~also~~ there is a great deal of time spent
9 on imaging of other organ systems, brain, lung, bones,
10 kidney, liver, et cetera. Again, very interesting.

11 I don't count the time wasted but it had very
12 little application to my own interest of cardiology so that
13 at least in that fairly restricted sense, I'm not even sure
14 that the 200 didactic hours are truly a requirement or a
15 necessity for someone who's going to confine his practice to
16 nuclear cardiology.

17 In Georgetown, as perhaps many of the other
18 speakers have indicated, we have a very comfortable working
19 relationship with the Nuclear Medicine Department.

20 We have cardiology for those nuclear medicine
21 fellows, radiology residents rotating through, and I'm
22 heavily involved in teaching all of these as well, of
23 course, as performing the cardiac tests. I think this
24 arrangement is a very comfortable one and one that certainly
25 is the ideal. I can't pretend to say that this should be a

1 DAVpp

1 requirement for everyone who wants to do nuclear
2 cardiology, and it's obviously the NRCs job and your job to
3 figure out exactly what the requirements should be for this
4 and other specialties.

5 I think that as much as possible, it would seem
6 to me, that the philosophy in back of your decision should
7 be to confine the Nuclear Regulatory Commission's
8 regulations to radiation safety as much as possible. This
9 has already been alluded to and I won't go into it further.
10 But I think clinical competency, as much as possible,
11 should be left to the professional organizations.

12 One point that I haven't heard alluded to so far,
13 and that is the way in which isotopes are prepared in
14 different settings. At Georgetown, we use a prepackaged
15 service for all of our nuclear medicine needs which, I
16 found, is very much more convenient for the physician. We
17 don't have to worry about all these quality control
18 aspects.

19 I wonder whether this shouldn't be something that
20 should be encouraged more widely. It certainly makes it
21 easier to practice, focusing on the clinical aspects of what
22 you're doing rather than having to worry quite so much about
23 the strictly radiation safety calibration, et cetera,
24 aspects of the procedures.

25 I think that's really all I have to say. Thank

1 DAVpp

1 you for the opportunity to speak.

2 MR. CUNNINGHAM: Thank you, Dr. Fox.

3 Dr. Holman?

4 DR. HOLMAN: Does your testimony mean that you
5 are supporting the position of the American College of
6 Cardiology and the American Heart Association?

7 DR. FOX: Yes, I do support their position,
8 although, my own personal feeling is that even a shorter
9 duration of formal training or required training would be
10 quite appropriate. It, perhaps, couldn't go back to what it
11 used to be, a three-month period, prior to all the changes
12 that were introduced.

13 MR. CUNNINGHAM: At the same time, you are
14 suggesting that it would be better to use prepackaged dose
15 forms rather than generators. Do you couple the length of
16 the training you subscribe to with the idea that you only
17 use prepackaged dose forms?

18 DR. FOX: I wasn't particularly coupling them,
19 although, I think that's something that your committee,
20 perhaps, should give some thought to.

21 MR. CUNNINGHAM: What would your position be on
22 that?

23 DR. FOX: Personally, I'm quite comfortable using
24 the prepackaged dose forms. I find it a real advantage not
25 to have to worry about all the other aspects. Whether that

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1 should be a requirement for a doctor who's not in the sort
2 of setting I'm in, whether that would be appropriate, I
3 can't say.

4 MR. CUNNINGHAM: Dr. DeNardo?

5 DR. DE NARDO: In your recent general nuclear
6 medicine course, I had several somewhat related questions.
7 Did you find that the bone imaging to be of any use in terms
8 of your use for these types of agents in cardiac work?

9 DR. FOX: The general principles^{LES} of imaging were
10 of some value, I think, but not the details of the more
11 specific aspects.

12 DR. DE NARDO: Did you get a chance to work or
13 see or be involved in either discussions or actual hands-on
14 in indium labeled blood cells?

15 DR. FOX: During that course there were
16 discussions. There were lectures, et cetera, but not
17 hands-on experience.

18 DR. DE NARDO: Do you think that would be of any
19 use, or would you be interested in doing one way or the
20 other, like indium labeled platelets requiring^{ed in (?)} artery
21 thrombosis or indium labeled antibody studies?

22 DR. FOX: We have discussed using indium labeled
23 platelets to detect thrombosis and so far have not felt that
24 it was worth the effort.

25 All of the difficulty involved in performing

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1 those specific tests, as I'm sure you well know, it's a very
2 tedious and time-consuming procedure. And we haven't felt
3 that it was warranted to try to set that up.

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1 DR. DE NARDO: Do you think your background,
2 training in general nuclear medicine has been useful in
3 helping to make, and in the future to help make, that sort of
4 decision on cardiac radiopharmaceuticals?

5 DR. FOX: I found the discussions on
6 radiopharmaceuticals in general quite interesting, yes, and
7 I'm sure they will be of some help to me.

8 DR. DE NARDO: Thank you.

9 MR. CUNNINGHAM: Captain Briner?

10 CAPT. BRINER: Dr. Fox, I gather from your
11 statement that you are not advocating that it be required
12 that physicians practicing cardiovascular nuclear medicine
13 use prepackaged dosage forms?

14 DR. FOX: No. I just threw that in as my own
15 experience and that it's a very neat way to practice. I'm
16 not saying that we ought to make this a requirement.

17 CAPT. BRINER: That's comforting because it's not
18 widely available in a lot of the lesser populated areas.

19 DR. FOX: I'm sure that's the case. In the big
20 cities, it's economically feasible to have companies that do
21 this for you.

22 CAPT. BRINER: But I hope you're not inferring
23 that you should not have any knowledge or interest in
24 quality control of the agents you use?

25 DR. FOX: Not at all.

1 CAPT. BRINER: And you feel you've had adequate
2 training to provide that?

3 DR. FOX: Yes, sir.

4 MR. CUNNINGHAM: Any other questions?

5 (No response.)

6 MR. CUNNINGHAM: Thank you very much.

7 Dr. Martinez.

8 DR. MARTINEZ: Mr. Chairman, members of the
9 committee. My name is Jose Martinez. I'm a physician. I'm
10 an internist with board certification in internal medicine.
11 I practice in Maryland in a 150-bed community hospital. I'm
12 also the President-Elect of the American College of Nuclear
13 Physicians and I'm testifying on behalf of the college.

14 The physicians of the college have had me send in
15 a document which has been distributed to you and I will not
16 reiterate it. But the essence of our position is that we
17 are in support of the reduction of the currently required
18 six-month training for physicians -- cardiologists wishing
19 to engage in cardiac imaging through the use of
20 radionuclides. We are in opposition to the reduction of the
21 six-month training period for all other physicians wishing
22 to practice nuclear medicine.

23 We, too, like other professional associations,
24 are very much in support of a single standard for radiation
25 safety and the proposals we support are in concert with that

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1 position.

2 The difference between the training requirement
3 of the two groups does not address the basic safety
4 requirement, the basic education, the basic body of
5 knowledge which is necessary to insure radiation safety.
6 And I could perhaps add at this point that, indeed, there is
7 an awful lot of transfer of knowledge between didactic
8 instruction and practical hands-on experience. But the role
9 of hands-on experience is not only to confer or transfer
10 knowledge, it is also to insure dexterity.

11 It appears to us eminently reasonable when a
12 physician states that his purpose is to perform only a
13 limited part, a limited number of procedures available to
14 him in nuclear medicine, that we should require that
15 physician to document for the Nuclear Regulatory Commission,
16 clinical exposure to only those procedures he can support.

17 We concur with the Nuclear Regulatory Commission
18 that it is not the intent of the Commission to certify
19 competence. We certainly do not believe that this is a
20 certification of competence, but what it does provide is an
21 assurance that the physician has had the opportunity of
22 translating his basic knowledge into clinical applications
23 and we find it quite reasonable to expect somebody who
24 wishes to engage in the broad field of nuclear medicine to
25 document if he has been exposed to a wider clinical

1 DAVpp

1 experience than somebody who wishes to limit himself to just
2 one discipline within the broad field of nuclear medicine.

3 The regulations under which we currently are
4 training were adopted after many years of discussion and
5 have been in effect only since July of 1984. They have
6 created severe problems for directors of training programs
7 in radiology.

8 We would be naive not to expect them to create
9 such problems in a discipline where there has been literally
10 an explosion of knowledge over the past 15 years. But they
11 have only been in existence for ten months, and we urge you
12 not to reverse them if enough experience has been available
13 to conclusively demonstrate whether they have beneficial or
14 detrimental training implications.

15 This concludes the position of the college.

16 If I may digress with your permission very
17 briefly to address my personal feeling about pre-packaged
18 doses, they are an extremely convenient way of taking
19 radiopharmaceuticals. I do not consider that they relieve
20 me or any other physician from the obligation from
21 personally assuring, at least on a sampling basis, that the
22 representations of the radiopharmacy are supported.

23 Thank you.

24 MR. CUNNINGHAM: Thank you very much,
25 Dr. Martinez.

1 DAVpp

1 I'm sure on your last personal statement you will
2 have strong support.

3 (Laughter.)

4 MR. CUNNINGHAM: Are there any questions of
5 Dr. Martinez?

6 If I may, I have a question for you.

7 You support the four-month training for nuclear
8 cardiologists but six-months training for the broader field
9 of nuclear medicine.

10 Now, as we see more specialty areas coming to
11 these as time passes, there will be other specialized groups
12 that want to use nuclear diagnostic or perhaps even
13 therapeutic techniques. Would you elaborate on nuclear
14 cardiology as a subspecialty in performance training to the
15 other areas where, if they want to use nuclear techniques in
16 a very narrow field -- would you support the idea of
17 four-months training in those instances?

18 DR. MARTINEZ: Again, Mr. Cunningham, I'll speak
19 for myself, not for the college.

20 We physicians must remember that what we are
21 granted is a license. It is a permit to perform such
22 functions, not license to perform functions that is absolute
23 freedom to perform functions. This process of licensing
24 reflects essentially societal concerns.

25 I do not look upon nuclear cardiology, really, as

1 a subspecialty but, rather, as the inclusion in the practice
2 of cardiology of a skilled procedure which the cardiologist
3 is able to perform well, and which benefits his patient.

4 As the body of knowledge in other subspecialties
5 grows, we probably will have to address the same question
6 elsewhere. I only hope that then we will be guided by the
7 same principles we're addressing today, that is, that the
8 training to which a physician is willing to submit himself
9 should assure us, as a society, that the services he will
10 render to the patient will be appropriate, will not result
11 in cost overruns -- a word we in medicine have to borrow
12 from the military today -- and that they will not result in
13 the redundancy of what is extremely expensive resources.

14 We do spend \$1 billion a day on medical care for
15 this country today and we have a responsibility for cost
16 containment. It's not vested in any one of us but it's
17 vested in all of us and we simply have to address it as it
18 comes along with the same integrity we address this one.

19 MR. CUNNINGHAM: Thank you very much.

20 Dr. Webster?

21 DR. WEBSTER: Following up on the question, could
22 you conceive of a specialist, another kind of specialist
23 requiring less than four months training? For example, we
24 do have physicians now who practice some aspect of nuclear
25 medicine under a general license.

1 DR. MARTINEZ: My personal experience and my
2 personal practice is under a specific license. Where an
3 institution has a broad license the delegation of the
4 responsibility for credentialing the physician is given to
5 the institution. Implicit in this is that each institution
6 develops its own criteria in compliance with rules,
7 regulations and laws.

8 I am concerned about the fact that an increasing
9 amount of diagnostic medicine is being practiced outside
10 hospitals and will increasingly be practiced outside
11 hospitals where the processes of credentialing, quality
12 assurance, and physician review do not exist.

13 Ipso facto the mechanism for regulating this
14 activity in society's benefit on the patient's falls back on
15 government.

16 If I may, Mr. Chairman, since I've been
17 recognized again, may I make a small point?

18 MR. CUNNINGHAM: Certainly.

19 DR. MARTINEZ: We are a bit concerned about the
20 fact that in the Federal Register's last notice of February,
21 only cardiology programs are designated as able to provide
22 the training of cardiac nuclear medicine. We understand
23 that this is not intended to disenfranchise training
24 programs in radiology. But we urge that in the final form
25 that regulations make that clear.

MR. CUNNINGHAM: The point is well noted.

You bring up a point, though, that diagnostic procedures are moving outside the hospital. I think Dr. Siegel brought out a good point in extending the broad license certification of physicians to other hospitals. But the trend seems to be have diagnostic procedures moving outside the hospital to clinics; is that correct?

DR. MARTINEZ: Yes, sir, they are known as cost-efficiency pressures that are brought to bear in this field. A freestanding diagnostic facility does not have to underwrite the cost of unreimbursed care. It does not have to underwrite the cost of training programs and education programs.

By definition the overhead of the freestanding facility is less than a hospital. In today's climate, this creates unsurmountable pressures to move the diagnostic exercises outside the hospital to the freestanding facilities.

MR. CUNNINGHAM: Thank you very much.

DR. MARTINEZ: Thank you, sir.

MR. CUNNINGHAM: Dr. Welch?

DR. WELCH: Mr. Cunningham, members of the Advisory Committee. My name is Michael Welch, Professor of Radiation Chemistry and Radiology at Washington University School of Medicine in St. Louis. I'm President of the

1 Society of Nuclear Medicine. I'm here to testify on behalf
2 of the Society of Nuclear Medicine.

3 The formal position statement of the Society of
4 Nuclear Medicine was sent to you prior to the meeting and is
5 the same as the ACNP statement, that is, to support the
6 ~~formal~~ ^{four month} training requirement for the practice of
7 cardiovascular nuclear medicine ^{and} ~~in~~ six months for physicians
8 practicing general nuclear medicine.

9 During my time, I'm going to give you some
10 backgrounds to the generation of this statement in the
11 Society of Nuclear Medicine. The Society contains members
12 from all of the groups testifying before you today. In
13 fact, the majority of people testifying on behalf of other
14 organizations -- as we have heard -- are, in fact, also
15 members of the Society of Nuclear Medicine.

16 Not only do members of the Society but members of
17 our Board of Trustees and Executive Committee have very
18 divergent views on this issue. The positions range from the
19 one supported by Dr. Blahd that the current regulations, in
20 fact, represent a compromise and that any misadministration
21 of radiopharmaceuticals impacts on radiation safety and so
22 that the current regulations should not be changed.

23 The opposite extreme is represented in the
24 testimony of my colleague at Washington University, Barry
25 Siegel. Since my installation as President of the Society

1 of Nuclear Medicine, the issue before you has been the major
2 topic discussed at our Executive Committee, Board of
3 Trustees, and in the many phone calls and letters that I've
4 received over the past ten months.

5 This issue has, in fact, consumed the major
6 portion of my time since last June and I strongly believe
7 that the joint ACNP-SNM position represents the only
8 possible change in the current regulations. With the
9 anti-nuclear sentiment in the general public, we believe
10 that altering the regulations affecting general nuclear
11 medicine -- especially regulations that have only been in
12 effect for a few months -- will be perceived as I say.

13 We do acknowledge that the Commission can grant
14 exemptions to the current regulations and that the
15 physicians solely practicing cardiovascular nuclear medicine
16 work~~s~~ with, and will always work with, less
17 radiopharmaceuticals than the nuclear medicine physician who
18 studies all organs.

19 It seems logical, therefore, that the training
20 necessary to allow the safe handling of a limited number of
21 radiopharmaceuticals and the clinical practice in order to
22 study them should be less than that required to handle all
23 radiopharmaceuticals for all organs.

24 This is the Society of Nuclear Medicine's
25 position. This has been a difficult and time-consuming

1 issue for the Society of Nuclear Medicine to discuss.

2 Even after our compromise position has been
3 reached, I am still receiving phone calls and, in fact, two
4 special delivery letters yesterday from members of the
5 society who hold what I will call the extreme positions. I,
6 however, strongly believe that when all the facts are taken
7 into account our position represents the only possible
8 change from the current regulations.

9 Thank you.

10 MR. CUNNINGHAM: Thank you very much, Dr. Welch.

11 Any questions?

12 Dr. Webster?

13 DR. WEBSTER: I read your statement very
14 carefully. I was impressed by the argument that you made.
15 You felt that in terms of the clinical limitations of the
16 field, that nuclear cardiology could get by, so to speak,
17 on less training -- four months. But actually, you didn't
18 mention four months, you just said less training.

19 But when you get right down to the end of your
20 statement -- almost the very last paragraph -- you suddenly
21 produce six months out of the air, so to speak, with no
22 logical build-up or lead-up or justification of the six
23 months. You could have said four months and three months
24 but you said six months and four months.

25 The only point you really made in your statement

1 was that it should be less for cardiologists but it should
2 be six months for other physicians.

3 DR. WELCH: If you look at the first paragraph of
4 my formal testimony, it states, "I'm sure you had an
5 opportunity to carefully review the November 8, 1984 letter
6 to Mr. Cunningham from the various specialty groups." And
7 we felt when making the formal statement that that was part
8 of the record and the arguments that are presented by the
9 Society and by the ACNP for the retention of six months for
10 general nuclear medicine are in that letter.

11 DR. WEBSTER: I didn't mean that at this time. I
12 had read it in the past.

13 My point is that you are really speaking to one
14 of two issues. One is, should there be a reduction of
15 time. Secondly, should the six months be maintained. It
16 seems to me that there are arguments for that that have to
17 be reiterated at this point in this climate in this
18 meeting.

19 DR. WELCH: I think that our position is the same
20 as the ACNP that was stated by Dr. Martinez that the six
21 months for general nuclear medicine was a position that was
22 reached after much discussion, after ~~readings~~ ^{meetings of} by this group.

23 That's a position that has only been in effect
24 for ten months and we feel strongly that ten months isn't a
25 long enough time to change this position.

1 MR. CUNNINGHAM: Dr. Woodbury?

2 DR. WOODBURY: One question. Whereas today the
3 question is relative to cardiology training, suppose next
4 year the field has progressed, let's say in hematology, so
5 that the hematologists and oncologists want to be licensed
6 to have antibodies and therapy training. Would you then
7 come back to this committee and suggest that we have a
8 separate form of training or period of training for that
9 group?

10 DR. WELCH: I think I mentioned in the statement
11 I just read, that the NRC does grant exemptions and that
12 each subgroup should be considered on its merits.

13 I would feel that, yes, if a group such as you
14 mentioned or even neurologists practicing nuclear medicine
15 should come along, they should be considered on their
16 merits. But I also agree with Dr. Martinez that four months
17 is probably the minimum because one always needs the core
18 radiation safety training and also some clinical practice.

19 MR. CUNNINGHAM: I would like to make a comment,
20 Dr. Welch, about how difficult it is, as current President
21 of the Society, to deal with opposing views until the
22 Society of Nuclear Medicine comes to a resolution on the
23 issue. I hope you have some sympathy for the NRC Staff.

24 (Laughter.)

25 MR. CUNNINGHAM: We understand warring

1 DAVpp

1 professional society and organizations.

2 DR. WELCH: I feel great sympathy for you. You
3 have the same people calling you wearing different hats
4 than they call me.

5 MR. CUNNINGHAM: Thank you very much.

6 Dr. Goodrich?

7 DR. GOODRICH: I would just like to recall for
8 everybody's memory, that indeed this Committee -- this
9 Advisory Committee -- heard the many hours of testimony and
10 the many days of efforts that went into communications
11 leading to the judgments that placed in the Federal Register
12 this July requirements for the six-month period.

13 I really would not feel that we would be required
14 to ask for further reiteration from the Society of Nuclear
15 Medicine or any of those bodies -- the justifications that
16 they presented at that time.

17 MR. CUNNINGHAM: Dr. Ross?

18 DR. ROSS: Thank you.

19 Good morning.

20 Mr. Chairman and Staff, members of the Advisory
21 Committee.

22 I'm Allan Ross, Director of the Division of
23 Cardiology at George Washington University School of
24 Medicine.

25 It is my feeling that nuclear cardiac imaging is

1 an important and useful diagnostic modality. I believe it
2 is best realized by individual physicians with appropriate
3 training in clinical cardiology, exercise testing, other
4 noninvasive methods, hemodynamics, catheterization,
5 angiography, recussitation, et cetera.

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1 But your position also requires the safe,
2 medically appropriate use of radio tracer materials. This
3 seems to be a universal provision. I believe that the NRC
4 Staff should duly issue an NRC licensure for the medical use
5 of isotopes independent of what appears to me to be much
6 medical politics, or as just stated, warring professional
7 societies. These should not be an issue for the NRC.

8 It is obviously advantageous for some individuals
9 to have federal regulations mandate an apparently excessive
10 training period. I think that's somewhat irrelevant.

11 I wonder why the NRC has not employed its
12 excellent staff to simply define the requirements necessary
13 to satisfy the NRC charge to protect the public health and
14 safety. It seems that the old regulations accomplished that
15 charter.

16 The clinical training aspects of diagnostic
17 nuclear cardiology procedures should be overseen by those
18 medical societies in residency and training responsible for
19 the overall training of specialized physicians. The safety
20 issues should be left to the NRC Staff.

21 I would urge the NRC to move in this direction so
22 medical politics are not the driving force behind any
23 government regulatory activity.

24 It's clear to me at this time that a training
25 period arbitrarily of six months to satisfy an NRC mandate,

1 DAVpp

1 at least in cardiovascular nuclear energy, is excessive.
2 And a two- or three-month training period should be more
3 than adequate, at least for that particular practice.

4 Thank you for affording me the opportunity to
5 offer my opinions.

6 MR. CUNNINGHAM: Thank you very much, Dr. Ross.
7 Questions by members of the panel?

8 (No response.)

9 MR. CUNNINGHAM: I have one.

10 In your hospital, Dr. Ross, what arrangements do
11 you have with other physicians, vis-a-vis who provides
12 imaging service and who interprets the image. How do you
13 work that out?

14 DR. ROSS: Well, at George Washington University
15 we have physicians licensed in the use of radioisotopes in
16 three departments, the Division of Cardiology, the
17 Department of Medicine in Nuclear Medicine, and in
18 Radiology.

19 For the majority of imaging modalities such as
20 those we're discussing this morning, the tests are all
21 performed under the direct supervision of cardiology faculty
22 members licensed to handle the material. The
23 interpretation is performed invariably in the large teaching
24 environment. Actually, the working interpretation is done
25 in a conference room with members of the Nuclear Medicine

1 Department, members of the Cardiology Division and trainees
2 from both disciplines, and it has been done that way since
3 the first image was made at our hospital.

4 MR. CUNNINGHAM: Dr. Holman?

5 DR. HOLMAN: Isn't it possible that your opinion
6 that two- to three-months training is sufficient, falls
7 directly from that wonderful cooperative venture you have
8 between radiology and cardiology?

9 DR. ROSS: My position that two- to three-month
10 would be perfectly adequate does not, in fact, at all relate
11 to our environment.

12 Where I think a logical approach at our
13 institution would probably be mandatory physics and safety
14 courses of, perhaps, 100 hours or 200. And that all
15 subsequent training requirements -- and that's what I mean
16 by I believe that is the role of the NRC to determine -- how
17 much time it takes a post-graduate physician to refresh on
18 physics and learn safety. And from that moment forward I
19 think it is a clinical issue; indications for tests, use of
20 the tests, interpretations. And I don't believe that there
21 will ever be a way to put a bracket or a number of months
22 around this increasing array of tests and subspecialists.

23 I think that the only logical way to do it is to
24 separate them entirely. I think it is probably best left to
25 training directors in immunology to decide how much clinical

1 DAVpp

1 training an immunologist might need, with hands-on
2 experience, to use these tests than for me or you or
3 anyone.

4 I think the issue before us today is the basic
5 safety of the training period in physics and safety. I, for
6 one, would think that it is my obligation to determine how
7 long a trainee of mine has got to work in my laboratory
8 before I feel that he is ready to go forward, having had the
9 safety instruction and the physics knowledge. Now I have
10 given him the clinical piece. I think I have to decide when
11 he can now perform those tests well and appropriately
12 without my supervision. And I dare say I would not want to
13 impose that limit, which for me might be two months, on the
14 immunologist or on an endocrinologist.

15 DR. GRIEM: Do you feel that operation of the
16 imaging equipment is part of radiation safety?

17 DR. ROSS: Yes. I think there is an element of
18 radiation safety involved in the operation of the
19 instrumentation just in calibration and in understanding
20 doses.

21 DR. GRIEM: I mean the actual thing that
22 generates the information that you interpret.

23 DR. ROSS: Would you mind restating your
24 question?

25 DR. GRIEM: Do you feel that the imaging

1 DAVpp

1 equipment is part of the process of radiation safety? In
2 other words, that this plays a role in radiation safety or
3 not? In other words, the imaging equipment is used.

4 DR. ROSS: Are we talking about the camera, the
5 computer?

6 DR. GRIEM: Yes.

7 DR. ROSS: Yes, I think they're involved in
8 safety.

9 MR. MC ELROY: How many labs do you have in the
10 hospital ~~to service~~ ^{that use} the various materials?

11 DR. ROSS: I can't even answer that. There are
12 numerous labs around the institution. Many of them, of
13 course, are research laboratories. There is a satellite and
14 separate lab for the nuclear cardiac imaging since it's all
15 done in my laboratory and is somewhat remote from the main
16 nuclear medicine department.

17 DR. WEBSTER: Following up on the instrument
18 question, who is responsible or who does, should I say, the
19 quality assurance on the imaging systems?

20 DR. ROSS: That is functionally a joint
21 enterprise.

22 DR. WEBSTER: Between who and who?

23 DR. ROSS: The Nuclear Medicine Department and
24 Cardiology.

25 DR. WEBSTER: I'm thinking about the

2 DAVpp

1 complimentary responsibility. What about personal
2 responsibility; who does it?

3 DR. ROSS: Three technicians who spend most of
4 their time -- and ~~they~~^{they} are nuclear medicine employees who
5 spend most of their time with us -- one nuclear medicine
6 physician and one cardiologist.

7 DR. WEBSTER: They are overseen by the clinical
8 staff in some way? Is there are some assurance?

9 DR. ROSS: They are the overseers.

10 MR. CUNNINGHAM: Thank you very much, Dr. Ross.
11 Dr. Garcia?

12 DR. GARCIA: My name is Robert Garcia. I'm a
13 practicing Nuclear Physician in the Northern Virginia area.
14 I have been in the practice of nuclear medicine for almost
15 25 years and have practiced nuclear cardiology for over ten
16 years. I have done this in conjunction with board
17 certified cardiologists and we have a very good working
18 relationship with the cardiologists whom I admire and
19 respect.

20 I would like to now read a prepared statement
21 from the American College of Nuclear Medicine, which
22 organization I'm representing today.

23 "The safety of patients subjected to diagnostic
24 and therapeutic procedures utilizing radioactive materials
25 and the reduction of radiation from such procedures to both

1 patients and medical personnel is of great importance to the
2 American College of Nuclear Medicine, to American physicians
3 and to all United States citizens. The optimum safe use of
4 radioactive materials in medical practice depends upon the
5 knowledge, competence, and experience of physicians who
6 receive formal training in radiation safety, radiation
7 protection, and quality control procedures prior to
8 licensure by the Nuclear Regulatory Commission.

9 "During the period of 1980 through 1982, many
10 organizations including the American Board of Nuclear
11 Medicine, the American College of Nuclear Physicians, the
12 American College of Radiology, the College of American
13 Pathologists, the Society of Nuclear Medicine, and the
14 American College of Nuclear Medicine, gave testimony or
15 statements to the NRC regarding minimal training standards
16 in radiation safety and protection. This was done by each
17 organization after a long and careful deliberative process.

18 "In 1982, the NRC established regulations which
19 became effective on July 1, 1984 which require a minimum of
20 six-months training and experience in the use of
21 radioisotopes for licensure.

22 "During the period of this regulation, there has
23 been a visible increase in the development of outpatient
24 40-hour-a-week, self-referral laboratories providing a wide
25 spectrum of nuclear medicine services. This has had a

1 DAVpp

1 considerable impact upon the full-service hospital-based
2 laboratory which must offer 168-hour service each week and
3 satisfy the strict requirements of the hospital
4 radioisotope committee for quality control and radiation
5 safety as well as those of the Joint Commission on
6 Accreditation of Hospitals.

7 "In many hospitals the use of technetium
8 generators in in-house radiopharmaceutical preparation had
9 to be returned to rather than use the more costly unit doses
10 supplied by local radiopharmacies at some increase in
11 personal radiation to the personnel in the hospital.

12 "It is the stated contention of the American
13 College of Nuclear Medicine that any further reduction in
14 training standards will have a widespread increase in the
15 use of radiopharmaceuticals in a less well-regulated
16 environment than the full-service hospital laboratory, and
17 yet this may be undesirable from the standpoint of
18 protection of the public from unnecessary medical radiation
19 exposure.

20 "The American College of Nuclear Medicine
21 continues the training standards set forth by the American
22 Board of Nuclear Medicine as the optimum for radiation
23 safety, radiobiological knowledge, radiation protection, and
24 would consider any further reduction in the training
25 standards from the six-month level as totally unjustified,

1 DAVpp

1 as no new scientific information to support that move has
2 been made apparent."

3 Parenthetically I would just like to add, the
4 American Board of Nuclear Medicine was established to
5 address the multi-disciplinary aspects of nuclear medicine
6 and was established as a conjoint board of the American
7 *Boards of Internal Medicine, Pathology and Radiology*, and
8 sponsored by the Society of Nuclear Medicine. And it is a
9 member of the American Board of Medical Specialties.

10 This conjoint board provides for a minimum of two
11 years -- 2,000 hours of training in nuclear medicine -- to
12 include no less than 200 hours devoted to radiation,
13 biology, nuclear physics, and radiation safety; to insure
14 the adequate protection of the health and safety of the
15 public from radiation hazards as mandated by the 66th
16 Congress and the Atomic Energy Act of 1954 as amended.

17 I stand ready to answer questions.

18 MR. CUNNINGHAM: Thank you very much,
19 Dr. Garcia. I'd like to ask a question first.

20 As I understood the first part of your testimony,
21 at least part of the basis on which you suggest a six-months
22 training program is to try to limit the number of people who
23 will engage in nuclear diagnostic techniques so that the
24 hospitals will have enough patient load to provide a full
25 range of services, rather than turning itself into private

1 DAVpp

1 clinics.

2 DR. GARCIA: That's absolutely correct, sir.

3 MR. CUNNINGHAM: Is this an economic question?

4 Is that correct?

5 DR. GARCIA: This is not just economic, sir. If
6 you have more patients being observed in outpatient
7 facilities, you're broadening the base of population
8 exposure.

9 MR. CUNNINGHAM: That's an interesting
10 observation.

11 DR. GARCIA: Not only that, but you will not have
12 the radiation protection committee, the radiation safety
13 committee, or the ~~joint chief of accreditation type~~ ^{Joint Commission on Accreditation of Hospitals -}
14 inspection³ of facilities[^] and supervising[^] of these facilities.

15 MR. CUNNINGHAM: I think those are arguable
16 issues but let me be sure I understood.

17 For the sake of argument, let's say that we agree
18 on that. I don't necessarily say we do but let's say we
19 agree on that. Would it still be your position that at
20 least in part these training requirements are useful to
21 limit the number of people engaging in these activities
22 outside the hospital environment; is that correct?

23 DR. GARCIA: No, sir. You're misconstruing what
24 I said.

25 MR. CUNNINGHAM: I don't understand what you

1 DAVpp

1 said.

2 DR. GARCIA: I said in order to protect the
3 health and safety of the individuals, we believe that an
4 optimum radiation safety standard needs to be established.
5 That seems to be optimally operating right now with the
6 community hospital.

7 Right now the community hospital is supplying the
8 bulk of the radioisotope examinations, however, in one of my
9 own hospitals -- due to the fact that outpatient facilities
10 have increased -- there has been approximately 60 percent
11 reduction in workload. These patients are being examined
12 now in an outpatient environment totally separate.

13 I, of course, have no control over the radiation
14 safety. I do know that because of that, I have had to
15 reinstitute quality control and cost-effective measures
16 which require the establishment of technetium generators and
17 so forth, ^{switching?} ~~willing~~ from unit doses. In order to compete
18 effectively, they have to operate 168 hours a week in our
19 hospital. We have to do the emergency lung scans, the
20 emergency GI bleeders in the middle of the night, as well as
21 the routine things.

22 I might parenthetically add that this statement
23 has very little to do with nuclear cardiology, as it was
24 nuclear oncology that was established and which diluted the
25 workload of the particular hospital I'm talking about.

1 DAVpp

1 So I think there are greater principles involved
2 and greater principles that you need to address than
3 looking at nuclear cardiology issues. These are the
4 viability of the community hospitals supplying a good
5 quality control program on a full 24-hour a day,
6 7-day-a-week basis so that all participants, all patients,
7 can be serviced with radiation safety and effectiveness.

8 MR. CUNNINGHAM: You believe this is something
9 that should involve the NRC?

10 DR. GARCIA: I absolutely do believe it should
11 involve the NRC.

12 MR. CUNNINGHAM: Any other questions of
13 Dr. Garcia?

14 Yes?

POHST:

15 DR. ~~MILLER~~: Dr. Garcia, can you tell me what the
16 American College of Nuclear Medicine is and how many members
17 it has?

18 DR. GARCIA: This is a college that was
19 established in 1971. It was the first college established
20 for nuclear medicine. I happen to be a member of two
21 colleges of nuclear medicine, the American Society of
22 Nuclear Medicine and the American College of Radiology and
23 the American Board of Radiology.

24 This is one of the organizations that I belong
25 to. It has about 800 members. It had, at one time, 1200

1 members. It is primarily composed of grass-roots physicians
2 who work in small community hospitals, as I perceive it at
3 this time, and who have been involved in direct patient care
4 of patients, as opposed to much of the testimony today, I
5 believe, came from university physicians who are not aware
6 of some of these changes that we've perceived at the smaller
7 community hospital level.

8 I'm sympathetic to the American College of
9 Cardiology in its position for this. I have nothing but the
10 utmost respect for the cardiologists and their involvement
11 in nuclear medicine. I think they've helped us move it
12 a long way and I would not perform nuclear medicine cardiac
13 studies without the assistance of a cardiologist.

14 We have an open staff arrangement with respect to
15 the cardiologists interfacing with us in that institution.

16 MR. CUNNINGHAM: Any other questions?

17 (No response.)

18 MR. CUNNINGHAM: Thank you very much, Dr. Garcia.
19 The next is Dr. Watson.

20 DR. GARCIA: I spoke for Watson. I combined
21 Watson and Allen.

22 MR. CUNNINGHAM: Dr. Griffin?
23
24
25

1 DR. GRIFFIN: Mr. Chairman, members of the
2 committee and colleagues, my name is Edmond Griffin. By
3 training, I am a research radiation biologist. By
4 profession, I am a radiation safety officer at the
5 University of Texas Science Center in Dallas, an institution
6 in which we have approximately 400 biomedical research labs
7 using radionuclides, and we have two hospitals in which
8 there are two separate nuclear medicine programs, and
9 combined, they perform more than 12,000 nuclear medicine
10 studies a year.

11 I appreciate the opportunity to make a comment
12 here, and rather than belabor some of the points of the
13 origin of the debate we have been in for a long time, I will
14 try to summarize mine as succinctly as possible.

15 In 1981 and '82, before the training requirements
16 were increased from three to six months, I commented on this
17 issue that radiological health and safety would be better
18 served through regulatory agency enforcement of, and training
19 programs' compliance with the three months training
20 requirement than it would by increasing the requirement to
21 six months, especially if there was no added assurance of
22 improved compliance, and I really haven't changed my
23 position since then.

24 While I accept the presently proposed requirement
25 of a four-month training program in radiation safety as

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1 being more than adequate to minimize unnecessary radiation
2 exposure, I remind all parties that my acceptance comes from
3 the expectation of full compliance with the letter and
4 intent of this requirement; that is, those physicians
5 requesting approval for the independent use of by-product
6 materials in medicine must perform and show documentation
7 that they have actually completed all aspects of the
8 training as described in the proposal.

9 In conclusion, I accept the establishment of and
10 compliance with the four-month training requirement as being
11 adequate and more than adequate for all physicians licensed
12 to use by-product material in medicine.

13 Thank you very much.

14 MR. CUNNINGHAM: Thank you very much.

15 Questions for Dr. Griffin?

16 (No response.)

17 MR. CUNNINGHAM: Thank you very much.

18 Finally, we have Dr. Johnson.

19 DR. JOHNSON: I am Dr. Philip Johnson. I practice
20 and have boards in internal medicine, endocrinology, and
21 nuclear medicine.

22 Cardiac problems make up a significant portion of
23 my internal medicine practice. On occasion I interpret
24 cardiovascular ^{imaging}aging results for a nearby hospital. I do
25 research, and I am in private practice.

1 For 20 years -- and the reason I am here -- I have
2 been a member of the Texas Radiation Advisory Board. Its
3 Medical Committee functions similar to this committee that I
4 am addressing now. Our committee's major problem is
5 verifying the quality of training, not the number of
6 months.

7 First, I will point out that I have no objection
8 to shortening the number of training months needed by a
9 cardiologist provided that this training is part of board
10 requirements. For a license to practice without the
11 umbrella of an institutional broad license, you must certify
12 that your training in nonclinical, defined by the NRC as
13 basic classroom training and supervised handling experience
14 and supervised clinical nuclear medicine, meet current NRC
15 requirements.

16 Generally, with board qualification in specified
17 specialties there is no problem, since required NRC training
18 is included in these American board director training
19 programs. These boards ensure institutional compliance by
20 rigid inspections. The regulatory authorities know that the
21 applicant has completed the required courses. Although a
22 passing grade is not required, it can be assumed that the
23 applicant will run a safe lab, and if not, it would be found
24 during an agency inspection. The preceptor, and in this
25 case the residency program director, would have no qualms

1 DAVbur

1 signing an appropriate certification because the residency
2 is American board approved and NRC accepted without
3 reservation.

4 When an applicant has not completed an NRC
5 specified residency, the task before the NRC, and in Texas'
6 case our Medical Committee, is to assure that the
7 applicant's knowledge is adequate so that the nuclear
8 medicine tests will be performed in a manner that is safe
9 for the general public, the radiation workers performing the
10 tests, and the patients.

11 The guiding role is obviously ALARA, mandating
12 minimal exposure to everyone, and an extension of the ALARA
13 philosophy requiring that the information justifies the
14 radiation exposure. Each applicant brings a signed document
15 indicating a training period at least equal to that listed
16 in the requirements.

17 While I would like to think otherwise, without a
18 board-backed training program, the preceptor signing the
19 license application has no easy way of knowing whether the
20 training was adequate, what the NRC means by basic
21 classroom training, whether the NRC requirements have
22 recently changed, and that the applicant's knowledge would
23 be enough to ensure a safe lab.

24 With only a vague idea of the regulations, as
25 noted by Dr. Beller, the preceptor does have a good

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1 knowledge of the applicant's supervised clinical experience,
2 since the preceptor sees this firsthand.

3 Lacking a board-mandated and prescribed curriculum
4 in the basic nonclinical training and experience, the
5 teaching is conventionally left to someone else, maybe in
6 the nuclear cardiology or nuclear medicine laboratories.

7 Since we know the application is often handed to
8 the preceptor as the applicant impatiently waits, any doubts
9 about competence are submerged or rationalized by the
10 signing. We wonder exactly what he is thinking when he
11 signs these papers. Without a board requiring basic
12 classroom training and supervised handling experience, it is
13 difficult to evaluate competence for licensure.

14 In Texas we have found there is no way out of this
15 verification dilemma. Certainly, we would not question the
16 professor of cardiology or radiology.

17 Therefore, I would suggest a departure from the
18 present licensure requirements. To me, it would seem wiser
19 not to force a specified number of training months, but have
20 the regulations require any application without board
21 credentials use outside experts with certain and acceptable
22 credentials. I would thus change the regulations to state
23 that in the absence of nonclinical training in the specified
24 specialty, the applicant must add to the application a named
25 responsible individual trained to and responsible for the

1 DAVbur

1 nonclinical operation of the proposed cardiovascular imaging
2 laboratory.

3 This responsible individual might be a health
4 physicist, a radiologist; it might be a nuclear medicine
5 person and would not have to know how to interpret the
6 cardiovascular imaging tests. This would be done by the
7 cardiologist.

8 The responsible individual would know the
9 regulations and how to run a safe lab. NRC inspection would
10 be of the responsible individual rather than of the
11 applicant cardiologist because inspections will continue to
12 be on laboratory practice and health aspects while ignoring
13 medical competence.

14 In large teaching institutions with broad
15 licenses, the nonclinical aspects of cardiovascular imaging
16 are generally not controlled by the cardiologists.
17 Therefore, my proposal is similar to the situation
18 encountered by a cardiology resident while he is in
19 training.

20 The NRC and ~~A~~greement ~~S~~tates can be reasonably
21 assured that anyone who is trained to practice cardiology
22 will interpret the nuclear studies in an intelligent way.
23 This is what is already being taught to the resident.

24 Somewhat like Dr. Siegel, we feel that adopting
25 this kind of a program will be in the interest of the

1 public, will be of help to Agreement States who may wish to
2 issue licenses to board qualified cardiologists, will
3 encourage cardiology, the field, specifically to include
4 nonclinical training in their residency program and will
5 help the regulatory agencies and other specialties who come
6 forth to request licensure of their own particular nuclear
7 imaging tests and dedicated laboratories.

8 Thank you.

9 MR. CUNNINGHAM: Thank you very much,
10 Dr. Johnson.

11 Are there any questions?

12 (No response.)

13 DR. CUNNINGHAM: Thank you so much.

14 We are very close to the lunch hour. I had hoped
15 we could begin discussions before that.

16 I would like to say, is there anyone who wants to
17 make about a two-minute statement who hasn't been heard
18 from?

19 (No response.)

20 MR. CUNNINGHAM: Good.

21 (Laughter.)

22 MR. CUNNINGHAM: The opportunity is lost.

23 At this point, I would propose that we break for
24 lunch now. We might get ahead of the crowd a little bit.
25 When we return, the committee will begin its deliberations.

1 DAVbur

1 What we will try to do in the course of these
2 deliberations is to establish a good record of the technical
3 or other bases for the various training schemes and also
4 rely heavily on the opinions of the various members of this
5 committee.

6 From this, the staff will subsequently try to
7 extract defensible positions which will be subsequently
8 promptly reviewed by the committee. I would anticipate it
9 would be reviewed by the Commission if there are changes
10 proposed and published for public comment prior to
11 adoption.

12 So recognizing that this is just the beginning of
13 a longer process, what we will try to do here is not make
14 decisions. That isn't the function of this committee, to
15 make final decisions on behalf of the Nuclear Regulatory
16 Commission, but rather it is to establish the scientific,
17 technical, economic, or other bases for making those
18 decisions.

19 We might think a bit about that at lunchtime
20 before we begin developing the basis for subsequent
21 decisions.

22 It is now five minutes till 12:00. I propose
23 there are a number of places to eat in this area. I think a
24 large number of them are fairly close.

25 I think everybody is going to want to get out of

1 DAVbur

1 here as early as possible this afternoon. Perhaps we can
2 reconvene at 1:15. That should allow adequate time, should
3 it not?

4 We will reconvene at 1:15.

5 (Whereupon, at 11:55 a.m., the meeting was
6 recessed, to reconvene at 1:15 p.m., this same day.)

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2 MR. CUNNINGHAM: Ladies and gentlemen, if you will
3 take your places, please, we should get started.

4 We have now heard from those who asked to make
5 statements before the committee, and I thank all those that
6 did participate. I think it was very helpful, certainly to
7 me and the staff and also to the members.

8 Now, we begin committee deliberations. I would
9 like to make these as informal as possible. I don't want to
10 exclude members of the audience from participation in these
11 discussions to the extent I can. We do want to move on
12 because we do want to stop at a reasonable time this
13 afternoon.

14 I know many of you -- in fact, most of you -- have
15 to travel from the city to get home, which is difficult on
16 the weekend.

17 As I see it, there are three decisions that the
18 NRC must eventually make with the advice of the committee.

19 The first of these is the length of training
20 requirements for the specialty of nuclear cardiology. That
21 has been specified broadly as four months duration, as
22 stated in the Federal Register.

23 Coupled with that, the question is raised of
24 whether or not it is appropriate to require only four months
25 for the more broad practice of nuclear medicine diagnostics,

1 since the radiological safety issues alone are very similar
2 for most types of diagnostic procedures as they are in
3 nuclear cardiology, even though there may be more
4 procedures, larger quantities of radioisotopes, and larger
5 patient doses.

6 The next question is whether or not other
7 specialized areas of nuclear medicine practice, diagnostic
8 practice should also be subject to four months training
9 requirements rather than six months if such criteria were
10 indeed adopted for nuclear cardiology diagnostic
11 ~~proceedings.~~
12 procedures.

12 Those are the three issues, I think, that the
13 staff must be prepared to address in any further alteration
14 of its criteria.

15 Now, there are two more things that we need to
16 bear in mind as these deliberations are to be made. The
17 first is that there are developments right now in nuclear
18 medicine that will probably become more widespread in the
19 early investigation stage or perhaps later in the
20 investigation stage in some instances relating to diagnostic
21 procedures related to some types of cancer and therapy for
22 certain types of cancers.

23 In a decade, probably we will see much more broad
24 use of these diagnostic and therapeutic procedures. We are
25 not simply planning for what the situation is now. Federal

1 agencies, as you well know, can be rather slow, so we must
2 think about the future.

3 The other trend that we should be very much aware
4 of, that is probably being caused by the economics of medical
5 practice and how patients' bills are paid, is the
6 relationship of hospitals to private clinics.

7 So the nuclear medicine practice -- there may be a
8 shift in nuclear medicine practice, which is largely
9 conducted at present in hospitals, toward private clinics,
10 and I don't think that the training requirements as such
11 will have a significant influence on that. It isn't
12 apparent to me, but certainly the economics of medical
13 practice itself will influence that change, and it appears
14 to be heading in that direction.

15 So we have to think about how patient care
16 delivery is going to shift over the coming decades as we
17 reach these various types of decisions.

18 Having said that and with the committee bearing in
19 mind these points, one thing that we might discuss some is
20 this gray area between requirements for radiation safety and
21 the quality of medical practice. That gray area is what, I
22 think, Dr. Bland referred to as the idea that if you perform
23 a diagnostic procedure on a patient that isn't needed or if
24 you misinterpret the diagnostic procedure, that patient has
25 received some radiation dose that provided no benefit to the

1 DAVbur

1 patient at best.

2 The question is: is that part of radiation
3 safety, or is that part of the quality of medical practice?

4 Perhaps this might be an area where we can start
5 discussion of ideas from members of the committee. Does
6 somebody want to start this?

7 Dr. Griem?

8 DR. GRIEM: Yes. The question that I put to
9 Dr. Ross, which we discussed this morning, is related to the
10 imaging equipment, which is part of the whole process of
11 information gathering for which an isotope is given to the
12 patient. He said it was part of the use of isotopes.

13 Is the sensitivity -- if such equipment were
14 operated at α^2 -fold less sensitive than it should be
15 operating at, then the dose to achieve an image would go up
16 by a factor of 2. As a matter of fact, the dose across the
17 board to the operator, the public, and everything would go
18 up by a factor of 2.

19 And what I am really getting to is the question of
20 quality assurance of the operation of such imaging
21 equipment, which also, I believe, is involved in radiation
22 safety, not necessarily image interpretation, and I wonder,
23 as we look at our requirements in basic science, if that is
24 emphasized enough.

25 Maybe Dr. Webster might want to expand on that.

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1 DR. WEBSTER: I thought about that since we
2 discussed it a few minutes ago, and I don't think we are
3 right, putting it bluntly. If you have equipment which is
4 off calibration, then you would just register a different
5 number of counts from the activity that you used.
6 Therefore, you would either get a higher count rate or a
7 lower count rate, but you won't change the dosage into the
8 patient. That has already been done. It is either
9 microcuries or millicuries. You will just get a different
10 image.

11 So I don't think it is a patient dosage problem.
12 I think it is an image quality problem.

13 In radiotherapy, if you have a machine which is
14 off calibration and you give twice as much dose as you think
15 you are giving, then the patient indeed gets more dose.
16 There have been a number of notable cases of malpractice
17 based on that.

18 But I don't think it applies to nuclear medicine
19 detection equipment. I am sorry I had to say that.

20 DR. HERRERA: Excuse me. In one sense, if you do
21 not control it, your machine is working suboptimally. If
22 you do a test and the result is poor, the likelihood it will
23 be repeated is much greater.

24 DR. WEBSTER: That is a question of what is a
25 satisfactory image and when is it so bad that you have to do

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1 DR. WORKMAN: In that sense, it is a problem of
2 radiation detection, don't you think?

3 DR. WEBSTER: It could be, if the image is
4 specifically unsatisfactory; right. And then it could be
5 very serious, because you might have to do a whole day's
6 work over again.

7 DR. HERRERA: May I address an issue that was
8 raised by Jim Christie this morning? You cannot talk, ~~it~~
9 is not realistic to think in terms of blocks of time. In
10 reality, the most prominent training on the integrating
11 basis over the length of the program. I think Jim Christie
12 is correct when he says it is not realistic to think of
13 these blocks of times, as if they were by themselves. An
14 indication, the likelihood is that the program in radiology,
15 a lot of the basic sciences are covered, not necessarily at
16 the time of exposure to nuclear medicine or radiation
17 physics, radiation biology. They must be covered somewhere
18 along the line.

19 So that confuses the issue of how long a period of
20 time.

21 The other issue, I agree also, is that clinical
22 competence is something that cannot be achieved in three
23 months, four months. For most of us, clinical competence
24 is a lifelong process, continuing and continuing. If we are
25 going to maintain some level of clinical competence.

1 DAVbw

MR. CUNNINGHAM: Dr. Holman.

DR. HOLMAN: Could I begin to address some of the issues you raised as the primary questions? I want to see how far we can get without addressing directly the stickiest point.

I'd like to begin by addressing one of the suggestions that was brought to us, and that was the most minimalistic approach with the least involvement of Nuclear Regulatory Commission. I personally feel that the involvement of the Nuclear Regulatory Commission has been very important in medical practice and its importance is going to increase with time. While it is true that in hospital practice there are now a number of safeguards provided by the medical community, these same safeguards are much less effective in office practice, as we see ourselves moving in the direction of diagnostic image centers and office imaging procedures. The ability at least of the ~~medical time of the~~ medical community to handle credential^s in this environment is minimal.

We can see that to some extent in radiology, other types of imaging procedures, but there is less involvement of the Nuclear Regulatory Commission and where, indeed, it has been shown that poorly trained individuals provide substantially higher radiation dose to the patient. And at least the potential is present for increasing patient

1 DAVbw

1 throughput by poorly trained individuals, increasing both
2 cost and radiation dose.

3 As far as the second issue, that of cardiology
4 training requirements, first of all, I'm very happy to see
5 so many of the important groups involved in this coming to
6 agreement on the issue. This is perhaps the first time
7 there has been such agreement since ^[the Aug. 1981 ACMUI meeting?] 1982 when the American
8 College of Cardiology first ^{opposed (?)} proposed six months of
9 training.

10 I think that all the groups involved, both the
11 Society of Nuclear Medicine, the American College of
12 Cardiology and the ACNP had much to lose by coming to this
13 rather unpopular compromise position, since, as we heard
14 today, there are many in each of the groups with rather
15 diverse opinions extending across the spectrum. So I think
16 that we and certainly the Staff at the NRC should think very
17 carefully about the recommendation of the Ad Hoc Committee
18 to go to four months of training as a compromise position
19 but one that has been addressed by individuals with a great
20 deal of experience, both from the cardiologic, radiologic
21 and nuclear medicine aspects of the problem.

22 I would think that therefore not to accept the
23 recommendation of the committee of four months would require
24 overwhelming quantitative information to the contrary, and I
25 don't believe that we've heard that in the testimony this

1 DAVbw

1 morning.

2 Finally, we're left with what I think is the third
3 issue. That is the length of training for involving in
4 general nuclear medicine applications. And here we've heard
5 much more diverse testimony, ranging from four months to six
6 months. If you heard carefully, probably testimony on each
7 side of those numbers, as well.

8 Perhaps we can dissect this problem into two
9 competing principles, two principles at war with each
10 other. One is, what is the proper length of training that
11 is required, and the second principle is, given the four
12 months of training for nuclear cardiology, do we wish to
13 institutionalize, more than it is already institutionalized,
14 the concept of a limited licensure. And I feel here that
15 since, as we've heard, it is most difficult to agree on the
16 precise length of time at which point ~~an~~^{of} individual is
17 adequately trained, particularly as we do now, by limiting
18 our ability to quantify that training, I think the second
19 principle, that of limited licensure, becomes the prominent
20 one.

21 I am most concerned about the idea of
22 institutionalizing one group with four months of training in
23 a limited aspect ~~and~~^{of} radio~~tracer~~ application, simply
24 opening up the way for other groups to come in, asking in
25 their own subspeciality or limited areas of practice for

1 DAVbw

1 less hours than are provided in the training for general
2 application of the tracer.

3 So I think whatever we do, it should be the same
4 number of hours for each, whether it is in the limited area
5 of nuclear cardiology or the general application of the
6 technique to all of nuclear medicine. How this should be
7 structured, I think is something that would be a little bit
8 difficult to generate at this time.

9 I might suggest that if we look at four months,
10 that comes out, as the report ^{has} ~~as~~ shown to 650 hours, I
11 certainly agree with the report that all the previous work
12 of this committee in coming up of 200 hours of didactics
13 should be maintained. The area that would most reasonably
14 be modified is the one of isotope handling, where 500 hours
15 certainly appears excessive and the number should be reduced
16 by some amount, and the rest of the training should ~~begin~~ as
17 it is now in clinical experience with radiotracer
18 applications.

19 MR. CUNNINGHAM: Thank you very much, indeed,
20 Dr. Holman. I think that's very helpful.

21 Did somebody want to comment on Dr. Holman's
22 comment, because I think it was very articulate.

23 DR. WEBSTER: Dr. Holman did say at the beginning,
24 with the patient in the private office, we tend to give more
25 dose. I think that is arguable.

1 DR. HOLMAN: I didn't say that. I said the
2 untrained user of radiotracers would be likely to give the
3 low dose and that the untrained person might more easily be
4 able to practice using radiotracers in the private office,
5 if the NRC were to pull out completely and not provide a
6 measure of certification.

7 DR. WEBSTER: That is different. What I was going
8 to say is that every package of isot^otypes has a package
9 insert which lists rather carefully the particular dose
10 indications, which I guess even an untrained person could
11 read. So that was the point I was going to make, but it
12 isn't quite so bad as I thought it was.

13 (Laughter.)

14 MR. CUNNINGHAM: Dr. Holman, I want to be sure I
15 understand.

16 You said toward the end of your statement that you
17 believe that no distinction should be made in hours of
18 training between a limited speciality, nuclear cardiology,
19 and general training requirements for nuclear medicine, that
20 is, radiation safety training. That's your position.

21 DR. HOLMAN: Yes.

22 MR. CUNNINGHAM: Frank? Dr. DeLand?

23 DR. DE LAND: I'm wondering. There is something
24 that's been bothering me for a long time. As you know, I've
25 been on this committee since it was formed in 1898.

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(Laughter.)

2 DR. DE LAND: We get these applications. One of
3 the things that bothers me is that I don't have the numbers
4 in front of me, but everyone of them got their 30 hours of
5 this and 10 hours. Did this ^{ever haunt (?)} hurt you? Nobody ever
6 got 42 hours of training. They got 40 hours. Nobody ever
7 got 98 hours of training. Nobody ever did 101 brain scans.
8 They all did 100 or 80 or 110. So this has bothered me for
9 a long time, the philosophy, and I think this was brought up
10 this morning, this philosophy that, okay, we're going to say
11 you're going to do two months, four months, six months, I
12 don't care what it is.

13 I wonder if that is really correct? I wonder if
14 the philosophy of the Board is not better, and that is, we
15 will look at a minimum time we think it is going to take you
16 to do something, but at the same time, you've got to
17 demonstrate your proficiency.

18 Now we have no problems with the American Board of
19 Radiology or the American Board of Nuclear Medicine. As
20 pointed out by Jim Christie and Barry Siegel, throughout the
21 Board it's not broken up into little tiny segments, except
22 perhaps for some of the didactic lecture series that you
23 get. It's all integrated in. You pick up a tremendous
24 amount of knowledge over two, three or four years, however
25 long you're at it. And you really can't differentiate that

1 at the time, but at the end of that time, then, what you
2 supposedly have gotten by direct contact, osmosis, or
3 what have you, you're going to find out by examination.

4 As I say, it bothers me a great deal. I'm sure
5 that a lot of these applications that are signed off are
6 not, shall we say, necessarily inaccurate. Whoever signs
7 them off doesn't pay any attention to them. I'm still
8 wondering that, rather than having a big battle over whether
9 we do three months, four months or six months, perhaps we
10 should look at just a minimum time and then no matter who it
11 is, they've got to show their proficiency. I think the
12 NRC has accepted the fact that if you have your ABRs and
13 your ^BANM, that that is evidence, and that you have received
14 and utilized sufficient information throughout the area of
15 the basic science, which may also include knowing how to run
16 an instrument. And I just threw that fourth.

17 To me, the way we've been doing this is
18 artificial.

19 MR. CUNNINGHAM: Of course, a regulatory agency
20 can only go so far. Certainly, board certification is an
21 indication of competence, but the NRC cannot exclude people,
22 physicians, who are not board certified from applying to use
23 these radioisot^opes. Unless we could show that, a strong
24 basis hasn't yet been demonstrated, that only
25 board certified certification is acceptable, I think we

1 would have to be prepared to consider this. Indeed, that's
2 why we have the qualification criteria. I've been around
3 this even longer than you, Frank, 1897, something like that,
4 but I recall working years ago with Merrill Bender in the
5 initial stages of getting Board certification in nuclear
6 medicine, and the objective at that time, my personal
7 objective and the objective of the organization, which was
8 the Atomic Energy Commission, was to enable us to withdraw
9 from regulating physicians at all, but it never worked.

10 One of the reasons it never worked was because the
11 physicians who were licensed to use nuclear medicine wanted
12 the AEC, now the NRC, to continue in this role.

13 So I would agree with the objective, but it hasn't
14 worked out that way.

15 DR. DE LAND: I wasn't promoting it or proposing.
16 it, ^{that} only the Board certified people to be licensed. What
17 I'm saying is, I think this method of just having a form
18 filled out -- you don't mind if I say all these things?

19 MR. CUNNINGHAM: No.

20 DR. DE LAND: This idea of just having a form
21 filled out and signed by somebody, you know, we got one the
22 other day.

23 MR. CUNNINGHAM: Don't name names.

24 DR. DE LAND: No names. We got one the other
25 day. You may remember it. The training was 15 years

1 DAVbw

1 earlier. Are you going to tell me that you remember 15
2 years ago that you gave him 40 hours of radiopharmaceuticals
3 and 20 hours, and 20 hours of this, and so forth?

4 So I'm thinking maybe the philosophy should be
5 changed, and we should have a better way to evaluate and not
6 just say, "Well, you've got to do this, this and that." If
7 it's written on that application form that he did this, this
8 and this, then we've got to sign off on this as acceptable.

9 MR. CUNNINGHAM: What are you proposing, Frank?

10 DR. DE LAND: What I'm proposing is, that the NRC
11 ^{come}~~me~~ up with some method, that the NRC come up with some
12 method that they can evaluate the actual training.

13 MR. CUNNINGHAM: Are you proposing that the NRC
14 administer tests?

15 DR. DE LAND: If necessary, yes.

16 (Laughter.)

17 DR. DE LAND: Now wait a minute. Our cardiology
18 -- to get down to the nitty-gritty, in cardiology, we
19 have said throughout this whole session, we will have to
20 admit there are certain, shall we say, training programs
21 where cardiologists go through it and are really not very
22 well trained. I am seeing them, and I'll have to disagree
23 with what somebody said there, that there ain't never been
24 no accident by a cardiologist. I had to tape up a whole
25 damn hallway, because of a board cardiologist who shot

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1 technetium up and down the hallway.

2 MR. CUNNINGHAM: It happens to nuclear physicists
3 too, who are not cardiologists also.

4 MR. DE LAND: I only want to make the point on
5 cardiologists, we have so many cardiologist here, and that
6 is, as far as board certification is concerned, on the
7 Cardiology Boards, they should have the necessary basic
8 science examination, if they are going to qualify their
9 people in nuclear cardiolog~~y~~y. If they do have, then why
10 would that not be acceptable?

11 MR. CUNNINGHAM: Dr. Webster.

12 DR. WEBSTER: I don't want to speak too much, but
13 an issue did arise this morning along this table about the
14 NRC inspection and the thoroughness of it. Inspections
15 right now are in strictly the radiation safety aspect. The
16 inspector comes around and looks at the people who have
17 got^ten more or less exposure, more typically, how many
18 spills there have been and what have you done wrong in the
19 waste disposal area, et cetera, et cetera.

20 But they do not look into training programs, in
21 my experience, and this might be one handle to grapple with
22 this problem. The inspectors, when they come around, should
23 actually try to document the amount of training that a given
24 institution which offers the training program is giving.
25 That would perhaps lead to great honesty.

1 We heard just now that these forms are signed as a
2 matter of rote without too much respect for the truth. That
3 would be my suggestion, that the inspectors take care of
4 that.

5 MR. CUNNINGHAM: Somebody from our inspection
6 office, I know Len Cobb was here earlier. Yes. Do you want
7 to come up to the microphone and let the reporter and
8 the committee know who you are.

9 MS. KARAGIANNS^I: ~~For~~ I&E has to go ^{on} ~~for~~ licensing
10 condition or written regulations. So unless the licensee's
11 license conditions says that we're going to have so many
12 hours of training for our physicians, I&E cannot ^{cite} ~~sign~~ on
13 that. So it has to be a regulation or a license condition.

14 MR. CUNNINGHAM: That is the problem. You can't
15 inspect the training program, unless it is part of the
16 by-product material license ^{of the} institution.

17 ^DMR. WEBSTER: I was thinking that there could be a
18 regulation introduced to cope with that. I agree that it is
19 one step away, but it's there, and it involves the sort of
20 things that people are licensed for.

21 So it is an important consideration, obviously.

22 MR. CUNNINGHAM: I think that this is dependent on
23 how this comes out. This is one of the things that we have
24 to look at. There may be some opportunity to do something
25 in that area.

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1 I'd like to -- in order to fully understand the
2 nature of the problem associated with training, I'd like
3 to ask the committee one or two questions.

4 Let's look at exposure of physicians, technicians
5 and members of the public, exclusive of the patient.

6 Our experience has been that occupational exposure
7 in nuclear medicine is, on the average, something less than
8 *[at the values permitted in 10 CFR Part 20].* 10 percent. Also, in my recollection, there have been very
9 few, and I can't even recall the specific incident, although
10 I am sure there are some, where a technician or physician or
11 a member of the public, other than ~~a~~ patients, received a
12 substantial overexposure due to accidents of one sort of
13 another.

14 Given this, how critical is the four-month
15 compared to the six-month training? I guess it is the other
16 way around. How much more protection are we going to
17 provide to this category of person, these categories of
18 people, by having six-month training as opposed to
19 four-month training in radiation protection?

20 Is this going to make a significant difference?

21 I am trying to break this in pieces now.

22 Does it make any significant difference?

23

24

25

1 DR. WORKMAN: I don't think we know, Dick. There
2 were comments this morning about how there had been no
3 spills, no problems and so forth, with nuclear cardiology.
4 particularly. But if that's so, that's based on six-months
5 training. So if it's not broke, why fix it.

6 MR. CUNNINGHAM: I think it's the other way
7 around, Joe, as a matter of fact. We receive today in
8 nuclear medicine -- as a whole, I don't know about the
9 cardiology speciality -- fairly low occupational doses.
10 Essentially no dose to members of the public.

11 This has resulted from the lower training
12 requirements we had previous to adoption of the six-months.
13 We haven't had a six-months training period that long so
14 that's what we're seeing.

15 The question is, for these categories of people
16 is that additional training appropriate. I don't see any
17 indication that it is. If members of the committee see some
18 indication, then I'd like to know about it.

19 Dr. Goodrich?

20 DR. GOODRICH: I asked Ms. ^{Vacca}~~Okker~~ this morning
21 about their experience in licensing ^{and} ~~inspection~~ ^{ing} facilities
22 other than the universities or the major medical centers,
23 i. e., the mobile units in the private practice sectors.
24 From her thoughtful reply, I gather that the vast majority
25 of activities that are defined as nuclear medicine that are

1 subject to inspection and licensure, are resting to date in
2 well-identified medical facilities, not small outlying
3 imaging centers, et cetera.

4 The thrust of my comment, therefore, is based on
5 the observation that in the setting of the university or the
6 300 to 700-bed private medical facility, there is an
7 environment of safety that is superimposed through the
8 health safety officers or the office of radioisotope
9 committees, et cetera, that supplements the knowledge -- or
10 I would say the trained awareness -- of the new physician in
11 training that he gleans from this very minimal health
12 physics training. ^{This} ~~The~~ proceeds from his program; ^{now} he's
13 operating in an ^{environment} ~~involvement~~ of safety that is maintained
14 through the offices of a rather large group of both
15 practitioners and physicists and technologists who are
16 trained.

17 That will not obtain in the imaging center or in
18 the private practice sector because, you know, one of those ^{their}
19 successes is their lack of administrative expenses, their
20 lack of need and the extensive support personnel that
21 fulfill the requirements at the hospital.

22 So I think that we need to have training
23 sufficient go to beyond the awareness of the need for those
24 support services. We need to go to the level of training
25 that will provide the implementation by the individual of

1 DAVpp

1 those safe practices rather than his being dependent and
2 accepting a very healthful environment.

3 MR. CUNNINGHAM: But that doesn't answer my
4 question. I'm trying to pin down whether or not the
5 additional training is going to make a substantial
6 difference in the amount of exposure these categories of
7 individuals receive. I'm going to get to the patient in a
8 little bit.

9 What we're dealing with --

10 DR. GOODRICH: I respectfully submit that that
11 did answer your question. To be more explicit, yes, I think
12 the additional training is necessary for the reasons I've
13 given because I see the future of medicine and the future
14 seat of the activities of medicine that we're discussing
15 moving significantly out into the private sector or the
16 small unit facility. And I think that the need for training
17 is sufficient to be able to implement on a personal basis,
18 is necessary. I don't see that as being achieved in the
19 prior three-month wonder programs.

20 DR. WEBSTER: I'd like to give a slightly
21 different answer to that.

22 This morning we heard several people say -- and I
23 think this is true -- that the additional time from three
24 months to six months which came into effect over a year ago,
25 was devoted to further clinical training not to further

1 training in radiation safety. That the 200 hours hadn't
2 been increased and the hands-on experience hadn't been
3 increased, but the clinical component had.

4 Therefore, I would submit that the increased
5 clinical training would have a rather small impact, if any
6 at all, on the exposures and the radiation safety issues,
7 the exposures people are getting. That would be my
8 impression.

9 MR. CUNNINGHAM: Dr. DeNardo?

10 DR. DE NARDO: Just to comment briefly ^{from} ~~on~~ my
11 perspective of what you asked in terms of exposure to
12 physicians, technicians, and the public relating to, in
13 particular, nuclear cardiology training requirements being
14 less than that for nuclear medicine physicians in general.
15 And I guess the other question being are the radiological
16 residents training in nuclear medicine?

17 The changes that I perceive when it was addressed
18 by Dr. Goodrich and the fact that the diagnostic center is
19 becoming a very important economic institution and is being
20 pushed by big business, it is happening all over and we're
21 getting there.

22 What I see in our area, at least, is the fact
23 that in the diagnostic center when someone frequently who
24 has less than maximum training, who has minimum
25 requirements, is sent there to set up particular types of

1 DAVpp

1 nuclear medicine studies and from his perspective awareness
2 of the things that he's setting up for now and for the
3 future, leaves much to be desired.

4 I bring that about in my thinking by looking at
5 what I expect to see, for instance, in nuclear cardiology.
6 There, we look at where are we now. Why do you see such a
7 low dose in the physicians, technicians, and any one of the
8 public who happens to be monitored. Like the secretary
9 sitting with a badge on her desk, I guess, because that's
10 the only way I know to get a reading on the public.

11 But technetium is what is being used at the
12 moment in most nuclear cardiology -- thallium by a few
13 people -- but most of the studies are technetium studies.

14 We've been lucky. Like with penicillin. With
15 technetium you can't do too much and get a high reading
16 unless you really do something terrible.

17 On the other hand if we look at the near future,
18 you certainly have heard a lot about antibody studies in
19 myocardial disease. I think we are looking at a lot of
20 possible indium studies of antibodies, platelets, various
21 types of receptor studies. We're looking at pharmacological
22 studies that I think are going to be a real thing, if not in
23 five years, within this decade. And we're looking at
24 physiologic studies with a lot of, I think, exceedingly
25 exciting but new and different isotopes.

1 And in standing on the threshold of all this
2 coming about clinically, we are talking about training
3 people to use technetium isotopes and calling that adequate
4 and I think that's having blinders on.

5 MR. CUNNINGHAM: Thank you very much, I think
6 that's very helpful.

7 Dr. Pohost?

8 DR. POHOST: I'd like to just make a few
9 comments.

10 First of all, I fully agree with Dr. Webster.
11 That is that the additional time is really devoted to
12 clinical activities which really doesn't change radiation
13 safety and hazards to the surrounding group of individuals.

14 Second, I think that nuclear cardiology, if I can
15 speak to that -- the experience of most of us is that
16 thallium is used very widely as well as technetium, and that
17 there are some new isotopes on the horizon. But I haven't
18 heard any of them mentioned -- that antibody studies are
19 not something that we anticipate ever using in nuclear
20 cardiology, that they're an interesting research and passing
21 fancy and perhaps they'll be useful for other organ systems
22 for cancer detection, but they're certainly not useful for
23 cardiac diagnostic methods.

24 Receptors and pharmacologic studies all sound
25 interesting but, really, from a clinical perspective, there

1 DAVpp

1 is no evidence that any of these things will have a role in
2 nuclear cardiology.

3 So I think for a long time past and for long time
4 from now on, the technetium and thallium will remain as the
5 principal agents of the nuclear cardiologists in
6 cardiovascular nuclear medicine.

7 I don't see anything on the horizon that has
8 stuck around for a long enough period of time to have any
9 hope that we're going to be changing those isotopes in the
10 future. There may be a technetium myocardial imaging agent
11 in the future but that's technetium.

12 I think if I could comment on a few other things
13 along with this, the indium and the indium labeled platelets
14 are also fascinating but not clinically relevant. Nobody to
15 date has shown any convincing evidence that they're very
16 important.

17 In addition to that, tomography -- that is,
18 single ~~meten~~^{photon} emission computer tomography -- remains a
19 research tool. Although there's some data that suggests it
20 may be marginally better for thallium studies, there's no
21 convincing evidence. It may, of course, be true that
22 positron emission tomography is far superior but that's not
23 the purpose of this discussion.

24 With regard to the boards, just one comment
25 here. I'm in the unique position of having taken both the

1 DAVpp

1 cardiology and the nuclear medicine boards. There were
2 questions on the cardiology boards about nuclear
3 cardiology -- even when I took them in the 1800s -- and the
4 in the nuclear medicine boards, at least when I took them in
5 the late 70's. I wouldn't rely on them to help us understand
6 someone's competence from a safety perspective. I think
7 they're inadequate mechanisms for documenting that someone
8 is safe versus someone who is not safe on the basis of pass
9 or fail of that particular board.

10 I passed it on the first time around,
11 fortunately, so I have a great objection to boards as being
12 the principal means for which you should decide if someone
13 is competent and safe in the handling of radionuclides.

14 On a different note, I'd like to point out that
15 the task force -- and I don't mean to switch gears. The
16 task force that you organized -- and I would like to
17 compliment you for having the ability to bring together the
18 people that seem to function well representing all
19 disciplines, cardiology, nuclear medicine, nuclear
20 radiology, radiology. This group functioned very well and
21 within a very short period of time, to all of our surprise,
22 came up with a very nice compromise position which seemed
23 very logical from each perspective.

24 But I would like to remind everyone that the
25 perspective that I came from was that the training

1 requirements just for the safe use of radiolabeled tracers,
2 were excessive at six months. And I still firmly believe
3 it's excessive at four months, and four months really
4 represents actually a compromise position.

5 I'd like to remind everyone that our original
6 position was we felt that it would be appropriate and safe
7 for individuals that didn't use generators, that used only
8 prepackaged agents to have, perhaps, two months of
9 training. And those who required the use of the generators
10 on the basis of experience of many years before, that the
11 three-months training period was, in fact, adequate. That
12 was our proposal.

13 I don't mean to open up a can of worms, but I
14 just wonder what the feeling is of the people in this
15 committee toward even lesser amounts of training for
16 competence in the area of radiation safety, particularly^L
17 with regard to dividing up the clinical issues which I
18 think we've heard today, and I believe strongly, should be
19 judged on the basis of training programs on an individual
20 basis versus the radiation safety issue, which the NRC is
21 interested in. And I'd like to really find out what the
22 opinion of the physics people on this committee is with
23 regard to that issue.

24 I think I've said enough.

25 (Laughter.)

1 DAVpp

1 MR. CUNNINGHAM: You said it.

2 (Laughter.)

3 MR. CUNNINGHAM: That's the end point.

4 I wanted to discuss some of these issues that
5 will lead us to that point in some logical manner but I'll
6 give Dr. Webster -- and Dr. Almond, perhaps may want to
7 respond since you asked the question of medical physicists
8 who are with us today.

9 Dr. Almond?

10 DR. ALMOND: This has been an interesting sort of
11 experience for me because it's somewhat outside of my field
12 of interest. But I think there are a number of points that
13 can be made. I'm impressed by the number of people who said
14 today that they really don't want to operate without the NRC
15 sort-of input. And you just pointed out a moment ago, this
16 goes back to the old AEC days.

17 We just don't have the baseline for any
18 information of using these materials when there weren't
19 regulations in force so it's very hard to say, have we
20 improved the situation or not? No one, I think, would want
21 to go without any kind of criteria for training and
22 experience to use these, so there has to be some minimum.

23 With regard to the sort of basic training and the
24 sciences, after 200 hours, it's a well sort-of established
25 sort-of time period that we have. By the way, talking about

1 the forms and Frank did this -- you didn't see the one that
2 came around the other day because it was in therapy. The
3 applicant had put 200 hours down for physics, 200 hours down
4 for mathematics, 200 hours down for biology, and 200 hours
5 down -- I happen to know the physicist who taught the
6 program and I said, maybe he had these guys in class all day
7 long. Obviously, I think people misread or just put down
8 what they feel the committee wants to see. It's very hard
9 to know when those forms are filled out, really, what the
10 training is.

11 The other thing about that is, though, you don't
12 know the quality of the training that these people are
13 getting. Some people can learn that stuff in 50 hours and
14 some it's going to take 250 hours, or 300 hours and it seems
15 to me there has to be a compromise on those hours.

16 I think for the physics and radiation protection
17 that 200 hours is, I think, a good compromise. Some people
18 get it in a shorter time; some people it takes a little
19 longer. I think it would be cutting it to reduce that
20 although in some instances I suspect you do get less.
21 But this is good training.

22 MR. CUNNINGHAM: Dr. Webster?

23 DR. WEBSTER: I'd like to talk to some other
24 aspects of that same problem of training, more in terms of
25 how the training is divided; how much do you spend on what

1 DAVpp

1 area.

2 Several people this morning, Dr. Siegel and
3 Dr. Ronan in particular, aimed rather sharply at the second
4 phase, 500 hours of hands-on training. I feel kind of
5 strongly about that, too. I think they're absolutely right
6 in what they said. It doesn't take 500 hours to do those
7 six or seven things, which Dr. Ronan spelled out.

8 For example, ordering and receiving and
9 unpackaging. You can learn how to do that in three hours
10 comfortably. Calibration of a dose calibrator and of a
11 survey meter, generously, a couple of days to learn that,
12 16 hours. I'll run down the list.

13 For the first six items, I think 60 to 70 hours
14 would be quite adequate. I mean, how long does it take to
15 learn how to administer doses to patients with shields and a
16 syringe. I was generous; I said four hours. And the last
17 one. There's one about ^{elution,} ~~illumination~~ assay, breakthrough
18 testing, and preparation of radiopharmaceutical kits.
19 There's a fair amount of meat on that one.

20 I believe that one probably by itself is more
21 important than all the others put together in terms of the
22 time demands. But I would allow two weeks for that. That's
23 80 hours.

24 My sum total for that whole program for the
25 second phase comes to 66 plus 80, which is 146 hours,

1 DAVpp

1 approximately one-third of what is being asked.

2 While the balance of the time could be used in
3 doing this clinical training, the balance of the four-month
4 or whatever is going to be decided in increasing the
5 clinical training component, because you've got a lot of
6 time left if you've only got 146 hours in that second
7 phase.

8 So that would be my attitude as a trainer, so to
9 speak, to the entire program.

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1 MR. CUNNINGHAM: That's very helpful and I'd like
2 to come back to this, Dr. Webster.

3 But before I do that, I see several people who
4 have got to leave. I think Dr. Siegel had his hand up a
5 moment ago.

6 One last shot, Dr. Siegel?

7 DR. SIEGEL: Actually, I might stick around for
8 little while longer.

9 Just a comment relative to your question about
10 the radiation safety to the general public and occupation
11 workers and physicians related to some of the things I
12 heard the committee saying. It bothers me a little bit and
13 I think we see the tail wagging the dog a little bit here.

14 We're talking about Appendix A of Regulatory
15 Guide 10.8 which is not the entire federal structure
16 for regulation of radiation safety. The remainder of Title
17 ¹⁰~~X~~ of the Code of Federal Regulations has a fair amount of
18 teeth in it and a fair number of very specific rules, some
19 of which we hope will be very clearly codified soon so that
20 everybody will have the same set of rules that they have to
21 follow. So physician training criteria alone are not the
22 primary basis for protecting the safety of the general
23 public.

24 One other point is, yes, nuclear medicine is
25 going to get more complex in the near future. All of

1 DAVpp

1 medicine is getting more complex on a daily basis.

2 Some of the things that Dr. DeNardo suggested are
3 going to happen and become part of practice may indeed
4 happen. A fair number of them, however, are not relevant to
5 this discussion because they're going to happen with
6 non-byproduct material and you all have no jurisdiction to
7 really be discussing this.

8 MR. CUNNINGHAM: I think, Dr. Siegal, that I
9 would agree with you that for protection of workers ^{and}~~in~~ the
10 public, there are a body of rules that must be complied
11 with. I think what Dr. DeNardo is indicating that without
12 sufficient training we will have physicians who don't know
13 how to comply with those rules and some other developments.

14 DR. SIEGEL: If I can just retort, I hope in my
15 statement this morning I was not misunderstood to be
16 suggesting that there be no physician training requirements
17 at all because certainly in the office setting where the
18 license is issued to the physician and where there is no
19 generalized institutional program of checks and balances,
20 then you have to have some starting place.

21 So, I absolutely say, I think my letter clearly
22 says that in the office setting, physician qualification to
23 insure safe radiation practice must be maintained.

24 I would just throw out the concept that in the
25 provider setting and institutional setting, it's conceivable

1 that they could be done away with.

2 MR. CUNNINGHAM: By having institution --

3 DR. SIEGEL: Having the institution take that as
4 part of its licensed responsibility and suffering the
5 consequences if they screw it up.

6 MR. CUNNINGHAM: I think your position has been
7 quite clear. We very much appreciate it.

8 The purpose I brought up, the occupational and
9 public exposure, what I'm trying to do is try to eliminate
10 those things from the controversy if we possibly can. I
11 think what Dr. Webster said is very helpful.

12 We also -- some of the things that Dr. De Nardo
13 said --

14 Dr. Woodbury?

15 DR. WOODBURY: I guess the reason most of us have
16 been reluctant to jump in and try to answer the question
17 with any definitiveness of exposure is because so much is
18 speculation. Early on when the Atomic Energy Commission
19 came out with a set of guidelines, it was in realization
20 that if not handled correctly, if the source was not handled
21 by persons trained, then it could inure to the deficit of
22 the population at large.

23 I think out of those rules and regulations we
24 have a reasonably good record of exposure but you really
25 need one untoward event to set the whole thing on its head.

1 For instance, in almost 15 years of practice I
2 never had a patient who asked about the effects of
3 radioactivity until the Three Mile Island accident. Then
4 the population became aware of exposure and so on and wanted
5 to know, did they glow in the dark and that type of thing.

6 In trying to answer your question ^{on} ~~or to~~ exposure, ^{ure,}
7 ~~you~~ it would all be speculation so we don't have hard
8 feelings [?] to predict what would happen in the future.

9 We do know the one thing that is certain is that
10 medicine, the practice of medicine, the practice of nuclear
11 medicine is changing; it's not as it was. We also know that
12 even at the time when the AEC began the regulations that
13 most of nuclear medicine was practiced in research centers,
14 the large centers. Now we know it's going to be
15 dispersed.

16 We also know that nuclear medicine regardless of
17 what form, whether it's cardiology or nuclear medicine in
18 general, is not going to be any safer and so to regress in
19 training would seem to me to be foolhardy.

20 I can't answer in terms of what we might expect
21 in terms of exposure. I can speculate as could anyone
22 else. It would seem to me to reduce the training that has
23 at least brought us the good marks we have so far. It would
24 be foolish to cut back.

25 MR. CUNNINGHAM: I should point out that let's

1 DAVpp

1 not lose sight of the fact that the six-month training
2 program has not been in effect that long. We are not seeing
3 the benefits of that additional training time at the
4 present.

5 The record of nuclear medicine and it's, I think,^a
6 good record with regard to protection of worker exposure,
7 exposure to the public, is based on training requirements
8 over the years that have been much less than the four months
9 that are being proposed now.

10 We simply aren't seeing what the six months will
11 do; what the ~~delta~~ is. I, myself, cannot see very much
12 difference, see much expectation of very much difference in
13 the quality of radiation exposure to workers and members
14 of the public added by that six months training program.

15 That's just one part of the picture. I'd like to
16 go to the other part.

17 Dr. Holman?

18 DR. HOLMAN: I think that we're spending a lot of
19 time talking about a given. The problem is so minimal as
20 you point out, with the three months of training that going to
21 ~~into~~ six was not the reason that somebody suggested you go
22 to it. So I prefer that we go onto the reasons.

23 MR. CUNNINGHAM: Let's deal with the tough
24 question and that is the patient.

25 I would like to hear from members of the

1 committee what they would expect to get in patient radiation
2 protection by six months training as opposed to four months
3 training; what they would expect to get or what they don't
4 expect to get.

5 Does anybody want to volunteer?

6 DR. HOLMAN: I have a question for you.

7 (Laughter.)

8 MR. CUNNINGHAM: You're not allowed to ask the
9 Chairman questions.

10 DR. HOLMAN: You have a baseline here because you
11 did that very nice misadmission of dose study in
12 association with ALARA to find out what the incidents of
13 misadministration is with three months of training but would
14 provide, perhaps, a basis for the rest of us to speculate.

15 MR. CUNNINGHAM: There are two things, of course,
16 I would point out, the ALARA requirements. That was made on
17 an occupational exposure. There was a misadministration
18 study following that.

19 For diagnostic misadministration involving
20 diagnostic procedures, I will make the generalization that
21 came out in a report just recently but in general the
22 misadministrations are associated with random human error.
23 We have not been able to pick a pattern which is subject to
24 correction by regulation or license requirements.

25 Typically, somebody gets a patient's charts mixed

1 up. They just simply misread a label. They pick the wrong
2 syringe out of the shield; they don't read it properly. And
3 it's random in most instances. There might be some
4 institutions that do that but these mistakes appear to be
5 random, human errors for unexplained reasons.

6 I don't know that an increase in training will
7 correct that. I'm not qualified to answer whether increased
8 training could change that.

9 In some cases, the technician misreads the
10 physician's handwriting which should induce physicians to
11 better penmanship, perhaps. That's happened in more than
12 one instance. But I don't see the relationship.

13 We haven't been able to draw a relationship of
14 these errors to training. As a matter of fact, we've gone
15 back through our license requirements and physician
16 training. In most cases, the physicians have what would be
17 considered very good training and many of them have been
18 conforming for years.

19 Bill, did you want to make a comment on this?

20 CAPT. BRINER: I've been waiting so long I've
21 forgotten what I was going to say.

22 (Laughter.)

23 CAPT. BRINER: But I would like to comment on
24 that misadministration Pandora's box that you just opened
25 and relate a part of that study, unless my memory's

1 completely failing me. The most significant number of
2 misadministrations in that original study were caused by the
3 output of a nuclear pharmacy and a physician accepting these
4 things without question and using them.

5 I pose the question: Would additional training
6 on the part of that ^{physician} ~~position~~ or those physicians have
7 prevented those misadministrations? Am I correct in that
8 statement about the nuclear pharmacy issue?

9 MR. CUNNINGHAM: I guess I have to answer that or
10 try to answer it.

11 Certainly, the first part of the problem is
12 dealing with the nuclear pharmacy that puts out nuclear drug
13 forms. And following this, we've taken some rather severe
14 enforcement action, or plan to do so, to the extent that
15 misadministration is also involved, the physician ^{and} ~~is~~ the
16 NRC. It also raises the question whether NRC requirements
17 for checking these doses should be changed. But I don't
18 know ^{that} it's really a training issue so much as a license
19 requirement issue.

20 I suppose one could argue that a more trained
21 physician would have suspected these things and checked them
22 independent of NRC requirements to check them.

23 I just don't know how to answer that part of the
24 question.

25 CAPT. BRINER: That was the point of my

1 question.

2 MR. CUNNINGHAM: And I don't know the answer to
3 that, Bill. Does anybody want to attempt to answer it?

4 Dr. Webster?

5 DR. WEBSTER: There's one anecdote from an
6 institution with which I'm very familiar. We had a rush of
7 three misadministrations last fall, that institution did. I
8 don't want to be cornered on that.

9 (Laughter.)

10 DR. WEBSTER: It was found that these were done,
11 these errors were made by probably the best nuclear medicine
12 technologists we have who blame human errors, in this case,
13 on the pressure of work.

14 Obviously, the training for this particular
15 person isn't going to have an impact. It probably wouldn't
16 have much impact on physicians. In this particular
17 institution, the physicians do not make the injections in
18 general.

19 Let me stop there.

20 That bears out, I think, the earlier comment.

21 MR. CUNNINGHAM: Before we leave this
22 misadministration, I might point out something to the
23 committee. There does seem to be an area where we will
24 probably come to misadministration. It has to do with
25 quality control of therapeutic doses. I don't want to

1 DAVpp

1 mislead the committee into saying that these
2 misadministrations have indicated nothing. I think there is
3 an area we need to explore further. We will probably be
4 coming back to the committee on that.

5 Okay, let's get back to the patients and
6 training.

7 As I understand it from some of the things I've
8 heard today, one of the issues that is perceived as
9 important in training is to prevent unnecessary exposure of
10 the patient either through prescribing procedures that are ^{not}
11 necessary or interpreting procedures incorrectly.

12 While that is very closely associated with the
13 quality of clinical practice, it can be argued that a
14 misinterpretation of the results of the procedure is, in
15 fact, giving some radiation dose to the patient without any
16 benefit.

17 Is this an important thing from a radiation
18 safety standpoint as opposed to the quality of clinical
19 practice, is a question for the members of the committee.

20 Dr. Pohost?

21 DR. POHOST: I think the issue is really one of
22 quality of practice and not one of radiation safety. That
23 is to say, knowing when a test is indicated and knowing how
24 to interpret it properly in the context of clinical
25 practice.

1 MR. CUNNINGHAM: Dr. Holman?

2 DR. HOLMAN: Performance of a unnecessary test
3 utilizing radiotracers obviously increases the radiation
4 exposure to that patient who had the unnecessary test.
5 Therefore, it's a radiation safety issue.

6 (Laughter.)

7 MR. CUNNINGHAM: This gives me just the answers I
8 need.

9 DR. POHOST: Let me say one other thing. It
10 becomes a radiation safety issue after the clinical mistake
11 is made but it's originally a clinical problem and if people
12 are not educated clinically, then they could make a
13 radiation safety mistake. But I think it's the problem, you
14 know, which is first the chicken or the egg and we're
15 talking about now the fact that the clinical problem is
16 driving the safety issue.

17 So, I think that the clinical issue is paramount
18 and the safety issue is secondary.

19 MR. CUNNINGHAM: So I understand your answer is
20 that, yes, it becomes a safety issue but the cause of the
21 safety issue is the quality of the clinical training as
22 opposed to the radiation safety training.

23 Let me ask Dr. Webster or Dr. Almond a question.
24 All these radiation doses we're talking about are evolved
25 stochastically; am I right, doses that are below the

1 non-stochastic threshold.

2 DR. WEBSTER: There would be no acute medical
3 effect. We'll be thinking about long-term.

4 MR. CUNNINGHAM: With a certain probability
5 associated with them.

6 DR. WEBSTER: Absolutely.

7 MR. CUNNINGHAM: Dr. DeNardo?

8 DR. DE NARDO: Just commenting on the issue we
9 had on the floor ~~remaining~~ ^{relating} to medical training being
10 necessary for the safe use of radioisotopes in patients.

11 The one area is that of retesting. In a sense if
12 a bad judgment call is made, in terms of how a study is
13 performed, either because the instrumentation is not
14 functioning right or because the patient is given the wrong
15 pharmaceutical because the judgment call was to do an indium
16 white cell study, but it should have been gallium.

17 We need to bring the patient back the next week
18 and do a gallium study, particularly a problem in children.
19 And vice versa, whether the gallium was used and it should
20 have been an indium white cell study or whether basically
21 good technique was not done and it was not caught by the
22 physician and the patient has to be returned for any of the
23 studies involved means that the patient is getting twice,
24 and sometimes more than twice, the injected dose of
25 radioactivity. And I think that's a radiation problem.

1 Yes, it was driven by the clinical problem but
2 that's why we're here, to practice nuclear medicine and
3 because patients have problems.

4 MR. CUNNINGHAM: Dr. Gould?

5 DR. GOULD: I want to just add an additional
6 answer to your question. Cardiologists face the decision of
7 cath, which involves a great deal of radiation exposure, in
8 many cases, more than in nuclear cardiology. We face that
9 as ^{do}~~to~~ radiologists, the same sorts of decisions.

10 I agree completely that radiation safety may be
11 related to the clinical problem. However, the ultimate
12 decision as to whether to go back for a repeat is a clinical
13 one. In my own experience, the specialists in the clinical
14 area making that decision, ultimately are responsible for
15 that second study or not, and certainly in cardiology almost
16 invariably the nuclear group will offer three or four more
17 tests which we have to make a clinical decision about,
18 because we're the ones that understand the physiology,
19 et cetera, that's necessary to make it.

20 So I agree that the radiation safety problem is
21 germane, that the solution is clinical competence which
22 really is not the area that you're addressing and that the
23 pure radiation safety part that has to do with doses, the
24 extra exposures if one drops the wrong syringe, that kind of
25 training is adequate for the shorter period of time.

1 MR. CUNNINGHAM: This is what we would like to do,
2 Dr. Gould. Separate clinical training from radiation safety
3 training. But, then, when I hear arguments that the lack of
4 good clinical training results in radiation safety problems,
5 that obscures that. And that's the difficult part.

6 I'd like to separate them. But, these kinds of
7 arguments lead us back into the quality of clinical
8 training.

9 DR. GOULD: I agree very much, if the NRC wants to
10 address the issue of clinical training, I would be happy to
11 participate in that discussion, if it has that jurisdiction.

12 I can say that the aspect of the decision of going
13 back for repeated studies, certainly, in cardiology, as I
14 understand radiologic training, that's a fundamental process
15 of training that we teach and learn every single day, for
16 now, in most programs, a three-year period of training. And
17 that the clinical training for the value of the given study
18 very much impacts that with our current program.

19 For example, many cardiologists don't use thalium^L
20 very much because they don't think the value is worth the
21 exposure and hassle to the patient, so they go on to another
22 study. And one can argue the technical merits of that. But
23 I'm saying that they are trained and fully exercising
24 expertise in making those decisions now, for which there is
25 an enormous record.

1 If you look at the AHA presentations and the
2 abstracts of the ACC, these are the very issues that these
3 trained people are addressing. So there are technical
4 differences but their exposure is really quite thorough,
5 very thorough.

6 MR. CUNNINGHAM: Dr. DeNardo.

7 DR. DENARDO: I'd like to clarify a point there.
8 If you decide you want your patient to have a study, do you
9 need the information provided by that study? You have made
10 a physician's judgment decision. If I do that study and
11 either let my technical staff, radiopharmaceutical staff, or
12 myself...excuse me, botch the job because of either the way
13 it's done, what's injected, or the way the information is
14 recorded, and I cannot give you the information, if you
15 needed that information in the first place, most likely you
16 will turn around, unless something has changed, and say, "I
17 still need the information." I have then caused the patient
18 to get a second dose of radioactivity.

19 And that's a little different from saying, "I've
20 done the study, and I have given you the information. Now,
21 do you want to get another study to give you different or
22 complementary information?"

23 That's another physician judgment call. I'm
24 speaking, however, in a repeat of the study, talking about
25 the studies and the many that are repeated, because of the

1 first study being done inappropriately, inadequately because
2 of basic problems in getting the appropriate data -- not
3 because it wasn't the right study to do.

4 And on the question I raised regarding the effect
5 of the disease process, that's another one. That's a little
6 more of a judgment call. But there are some basic things in
7 training that yield definite information that isn't followed
8 by people who haven't had both the clinical and the pre-
9 clinical training to make those decisions.

10 And that one gets repeated when such things happen
11 as a patient with a low white count gets her blood drawn,
12 sent outside to lab X, who doesn't know that there's no
13 white cells, sends back indium on good gracious knows what,
14 and it gets injected; instead of getting a white cell scan,
15 you get a gmish.

16 That is again a technical education problem. I
17 don't think that is a clinical judgment call, it's just
18 basically not knowing the things and not, not thinking about
19 the things to look for.

20 DR. GOULD: I think we're in complete agreement in
21 terms of if the job is done by really good technical people
22 there's no question. The reason that I run the entire
23 nuclear cardiology is because there is only botched cases by
24 the nuclear people that did not understand fundamental
25 clinical problems; similarly, just interpretations, or

1 whatever, but were off the wall. There was not the
2 fundamental clinical competence to bring it off.

3 So I think if one is competent, I've got no
4 problem. But, to define that by a set of rules other than
5 the requirements of good clinical training, I think, is
6 *competence(?)* beyond the comprehension of the NRC.

7 MR. CUNNINGHAM: Mr. Dorian is a member of our
8 legal counsel at the NRC and I would just like...

9 MR. DORIAN: I'd just like to bring a little bit
10 of perspective from the nuclear reactor area into this area
11 as well, and then to make another point.

12 As to the perspective we found in connection with
13 operators who run nuclear power plants, that it's very, very
14 important to have quality control and quality assurance in
15 their training programs; so that the quality of training, as
16 the point has I think been made before, is very important,
17 as are, of course, the number of hours perhaps more
18 important.

19 The other point from the nuclear power plant area
20 that's important to remember is that recertification is very
21 important. Once someone has had training, just because
22 they've had training, 20 years later, they may forget it.
23 The area advances, things change. I would like to add
24 another perspective, that recertification is important.

25 Finally, the pragmatic point. NRC is in a

1 DAV/bc

1 difficult position with respect to the public and with
2 respect to Congress. I think the doctors realize that.

3 And the pragmatic point is very, very simple.
4 Once the NRC has gone so far as to raise the threshold of
5 training from four to six months, it would be very, very
6 difficult, I would say, wel, ^{nigh}~~ne~~ impossible to lower it
7 again.

8 MR. CUNNINGHAM: What Mr. Dorian said was public
9 concern about nuclear activities in general, once you set a
10 high standard for training, it is very difficult if not
11 impossible to go to what appears to the public to be a lower
12 standard. Whether it is or not doesn't matter. We all have
13 had experience. Those of us on the NRC staff have had that
14 experience of this kind of thing in recent years.

15 It isn't nearly so difficult to put on additional
16 requirements in regulating nuclear energy as it is to remove
17 such requirements.

18 DR. WEBSTER: There's an issue on the other hand
19 which can be made with the opposite point, namely, that a
20 couple of years ago the waste disposal of low level carbon-
21 14 and tritium were deregulated so they could be treated as
22 nonradioactive. That might be considered a step backwards.

23 Certainly, it was unraveling some regulations
24 which already existed. So it isn't impossible. And that's
25 not the only example of a reversal.

1 MR. DORIAN: As Mr. Cunningham said, my point was
2 that wasn't a public perception.

3 DR. WEBSTER: There was public concern, but it
4 didn't win the day.

5 MR. CUNNINGHAM: That is one time when this was
6 successful. As a general principle, I think Tom correctly
7 points out that it's very difficult to go to a different
8 standard. I think the point he's making, and you have to
9 consider this, Dr. DeLand has indicated that it isn't the
10 hours, it's the gravity of the practice and the quality of
11 the training.

12 A number of people have said...I think Dr. Collins
13 has said in the past, that, really, it is what the person
14 learns rather than how many hours of training that he's had
15 that is the important thing. The issue we always confront
16 is how does a regulatory agency measure or regulate this
17 kind of thing?

18 Now perhaps the hours or length of training don't
19 even need to be prescribed if we had to define the types of
20 training. The broad subjects of the training, if we could
21 devise some method to put quality assurance in the training
22 programs and some way of determining that a person who goes
23 through this training program has indeed learned what he's
24 supposed to know.

25 Dr. Holman.

1 DR. HOLMAN: I think this is really the critical
2 issue of trying to put quality in the package. It would
3 certainly make a lot of us more comfortable one way or the
4 other. What you're suggesting, by eliminating the hours
5 altogether, makes it almost necessary to have some kind of
6 competency, which I don't think you want to get into.

7 I was wondering, part of the recommendation of the
8 task force was simply to limit separate training within
9 structures of approved resident ~~cy~~ programs. Maybe that in
10 itself might be one way to do it, by disfranchising the
11 unapproved programs, if that sort of thing could be done.

12 MR. CUNNINGHAM: Do other committee members have a
13 comment on what Dr. Holman just said? Where I'm leading is
14 that if we are to move from the six month training, do we
15 have a basis for doing so by better ~~issuing~~ ^{ensuring} quality in the
16 training program?

17 DR. HERRERA: May I address that issue?

18 There are other specialties in medicine, and I'm
19 not suggesting that the government should do it. I think
20 it's my own bias that this can be better done by
21 professional societies. But the fact remains that,
22 specifically, there are the so-called laboratory medicine or
23 clinical medicine where, in addition to what they were
24 trained, unless you have in place quality control programs
25 both internal and external, no matter what your background,

1 DAV/bc

1 experience and training is, the number of errors in your
2 case would be translated into additional radiation
3 ~~anticipated participation~~, all ^{un} necessary application of radiation, if,
4 in addition to the initial training of the individuals
5 involved, there is ^{not} in place a program of quality assurance
6 and quality control.

7 In the case of the technologies, we go as far as
8 having created a program on a voluntary basis where we are
9 constantly surveying proficiency in performance of various
10 laboratories in the country.

11 I know that by saying that, half of my friends in
12 this room may never speak to me again. And I'm not
13 suggesting at all that the Nuclear Regulatory Commission
14 should undertake this task, because I believe that Nuclear
15 Medicine professional societies can develop appropriate
16 programs to provide quality assurance and quality control.
17 Without that, there will always be mistakes, no matter what
18 the training is; because people, like the universe, follow
19 the second law of Thermodynamics. No matter where you
20 start, you end up in the sack unless there is some prodding
21 that keeps on.

22 DR. DELAND: I'd like to reinforce what the
23 attorney said. Yes, they did relax the carbon-14 tritium
24 problem. But, at home, at any rate, just as soon as it came
25 out, it was turned down by the public, even though federally

1 DAV/bc 1 it is actually preferable.

2 The other thing is I appreciate the fact, the
3 conversation, as far as I can see, is going toward perhaps a
4 less fixed idea in either time, hours or value. I can
5 appreciate the fact that the NRC does not want to get into,
6 or perhaps it is not permissible for them to get into any
7 type of objective evaluation that's in written form.

8 Perhaps something that might be investigated is if
9 the group that came through this compromise, perhaps they
10 could come up with their own program that is applicable.
11 After all, it is applicable to cardiologists, in nuclear
12 medicine people, radiologists and so on. I would think they
13 would come up with their own program that is initiated
14 within all the training programs.

15 And for the young men and women that are under
16 training, that, in anticipation of their getting NRC
17 approval, that they are examined through the good auspices
18 of the ACC, the ACR, the SNM, and so on. And unless they
19 stand or die, then the NRC can accept it and say, Well,
20 whether they have the boards or not, they have passed an
21 exam that all of us have agreed to, that it is objective and
22 shows that they've got the training.

23 By the way, I think training is not so great. But
24 the NRC is not involved in this other than the fact that
25 they have a recommendation from people who know what the

1 program should be and what the people should know before
2 they let them loose.

3 MR. CUNNINGHAM: Thank you very much, Dr. DeLand.
4 Does anybody else want to comment on this?
5 Dr. Gould.

6 DR. GOULD: You asked for a suggestion as to how
7 one would in a sense defend the six-month as opposed to
8 four. I would suggest one alternative would be that the
9 original extension of three months was concerned with
10 further clinical experience at that time.

11 But, now, with larger input from the American
12 College of Radiology, which I've already gone through, as
13 Dr. DeLand suggested, and all these other groups, with
14 further input from them, you ~~X~~now have the judgment from a
15 larger sample that would indicate that the more limited
16 period of time is certainly adequate for safety if one
17 restricts its point of view to those aspects.

18 In that way, one really isn't reducing the
19 requirement for safety but is detailing an evolutionary
20 sequence of ideas by the NRC.

21 DR. WEBSTER: On the question of assuring the
22 quality of training programs, of course, the various boards
23 have an arm, so to speak, to do that. They have the
24 residency review committees. They presumably, and I don't
25 know just how deeply these reviews go, but I know they look

1 DAV/bc

1 at the quality of equipment, the space and the personnel,
2 and the amount of time put into different areas -- whether
3 or not that should be communicated with the preceptor's
4 report to the NRC is something else.

5 You might not want that kind of information to go
6 to a government agency. Nevertheless, it would be one
7 hallmark, so to speak, of a good training program, that they
8 have passed the review of the Residency Board.

9 DR. HOLMAN: The Residency Review Committees are
10 not set up by the boards. They have various sponsorships.
11 In many cases, the boards are one of the sponsors, but, in
12 any case, that was my original suggestion. What the
13 residency review committees do is simply determine the
14 adequacy and quality of residency training programs.

15 Once approved by the residency review committee,
16 it is then essentially an approved program, approved
17 ultimately by the ACGME, ~~the~~ The Accreditation Council for
18 Graduate Medical Education, that was precisely my point.
19 Such accreditation at least ensures that there is a critical
20 mass there to provide the kind of training we're talking
21 about, the kind of training in radiation protection,
22 radiation biology, physics instrumentation, the basic
23 sciences, as well as the clinical training.

24 And it would at least provide a semblance of
25 assurance that there is the staffing there to provide the

1 DAV/bc

1 minimum requirements.

2 At the present time, it is my understanding that
3 the training, at least for those individuals who do not come
4 to us under the aegis of the American Board of Radiology or
5 the American Board of Nuclear Medicine would have their
6 training under any preceptor that is licensed by the NRC.

7 And I think that to gain some semblance of quality
8 control, limiting the training to at least a facility which
9 has an approved training program would be a useful step.

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1 MR. CUNNINGHAM: We're drawing close to 3:00
2 o'clock. I would like to draw this meeting to a conclusion
3 fairly soon, because I know people have planes to get.

4 Do you have a comment?

5 DR. MITCHELL: My name is Thomas Mitchell. I have
6 been involved in training ^{of} ~~and~~ nuclear medical ^{physicians} ~~positions~~
7 since 1956, across the street in Bethesda with Dick King and
8 since 1969, I have been at Johns Hopkins Medical
9 Institutions. I am currently the director of academic
10 training in the Division of Radiation Health Sciences.

11 I think there are a few things I would like to
12 comment on. Number one, concerning the physicians. We have
13 all been talking about training. I think there is a certain
14 amount of training involved with physicians in nuclear
15 medicine and the radiation health sciences in general, but
16 by and large, when a physician is in a residency program, it
17 is really a educational program.

18 I see education has broader than training. I see
19 education as a means of approaching problems through a
20 particular discipline. A lot of time has been spent here
21 with respect to training. I think about training, I think
22 about dogs, I think about horses and lions, and I think
23 about technologists. I think about people who are being
24 trained to do a particular task. When I think about
25 educating someone, I don't think he has to get 100 percent

1 of all material I give to him. On the other hand, when I've
2 training someone, I want him to get 100 percent of the
3 need-to-know material and limit the nice-to-know material.

4 I think part of the problems here with respect to
5 filling hours has to do with giving out a lot of information
6 which is nice to know but not need to know. I certainly
7 don't think nuclear cardiologists need, for instance, 20
8 hours of training in radiation biology. Under other
9 circumstances, say, in terms of passive defense, in terms of
10 potential weapons attacks, there may be some need for that,
11 but the training requirements are set up on the basis of
12 hours that I think are completely wrong. What I would
13 rather see are some performance criteria, particularly with
14 respect to safety.

15 I am talking about safety with respect to patient,
16 physician, the worker and the general public. Some of this
17 could be solved very, very easily by some slight changes in
18 the agency's 313-M, ~~The~~ AEC 313-M; and we had a fair number
19 of formal graduate-level courses which are for radiologists
20 and for our nuclear medical ~~positions~~ ^{physicians} to take.

21 I have a little form for them, which says, if you
22 took 18-A 68, then you have X hours of radiobiology and Y
23 hours of physics and three hours of mathematics and so on.

24 Now, that form is of some limited value, but just
25 as for a recommendation, when a physician or a graduate

1 student is leaving and going out, you can't use a standard
2 form to tell what that person is capable of doing and not
3 doing. I would like to see some things added to 313-M,
4 particularly for those physicians who are going out into
5 private practice, where they are not going to be under a
6 license, where they are not going to have benefits of radio
7 pharmacists nor radiation physicists. And I would like to
8 fill that out knowing what technical help is going to be
9 available for them.

10 The Nuclear Regulatory Commission has also
11 realized the value of Board certified physicists in doing a
12 very simple procedure, that is the calibration of
13 teletherapy apparatus. Shouldn't the therapeutic
14 radiologist be able to do his own calibration? Why does he
15 need a board certified radiologist to do a very, very simple
16 thing. Well, the point of this is, you will already
17 recognize that there are specialists who are going to
18 provide certain facilities, I think in the area of
19 radiopharmacy. Those of you who are physicians don't
20 compound your own drugs anymore. There are any number of
21 pharmacists who can be trained very, very easily to do
22 radiopharmacy. I am surprised that there are not more
23 pharmacists who have been trained in radiopharmacy.

24 Why should the physician have to be responsible
25 for his own radiopharmacy?

1 The other major problem, and this is the one I am
2 going to ⁹step on, is the area of self-referral. This is one
3 of our biggest problem that I would worry about, if I looked
4 at people who are licensed out in the community. That is,
5 are they referring them to themselves or are they
6 referring to patients from other physicians.

7 If patients are being referred to them from other
8 physicians, then the marketplace is going to determine if
9 they are incompetent, they are going to go out of business.

10 That is all I want to say. Thank you.

11 MR. CUNNINGHAM: Thank you very much.

12 I would like to attempt to summarize or poll the
13 committee on a couple of points, in order to wind this thing
14 up, but prior to do so, I would like to know if there are
15 any further comments.

16 Dr. DeNardo?

17 DR. DE NARDO: I think there is one thing that I
18 wanted to just bring forward for the record today, which we
19 have not touched on. That is, the potential and at least
20 the growing obvious area of therapeutic nuclear medicine.

21 One can first point out that a lot of licenses
22 will exclude the use of therapeutic materials and others
23 will not. On the other hand, the influx of therapeutic
24 methodology in nuclear medicine above and beyond the
25 techniques that were developed 20 years ago has already

1 started and has started in other countries even more than it
2 has done here.

3 Part of that developmental technology has led them
4 to diagnostic tests with small amounts of these therapeutic
5 isotopes, and I think that will also add another dimension
6 to the problems that we see today, in terms of radiation
7 assays.

8 MR. CUNNINGHAM: Thank you, Dr. DeNardo.

9 Dr. Schlant. I think these comments should be
10 held fairly briefly now, because we do need to close the
11 meeting.

12 DR. SCHLANT: The question is, a program can be
13 inspected and deemed competent. That doesn't necessarily
14 mean the people going through it are competent. A test of
15 competency, if you had a few questions on a large one-day
16 examination, where you may have three or five questions on
17 radiation safety, a person could easily miss every one of
18 those questions and still pass the examination and be "Board
19 certified."

20 If you want to give an exam on safety, you'd have
21 to design a whole separate examination on that, not part of
22 a nuclear medicine examination or cardiology, but a whole
23 separate one, which is a very difficult thing. I don't
24 really think any of the current ones are really ^e that proper
25 testing techniques, really evaluating competency in

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1 radiation safety. So these are some of the dilemmas that
2 even approval of the program or passing a Board exam doesn't
3 necessary^{il} approve that individual. You still need a letter
4 of personal recommendation from the director and some faith
5 in his qualities.

6 MR. CUNNINGHAM: Thank you. Dr. Griem?

7 DR. GRIEM: Concerning therapy. The American
8 Board of Radiology has a written exam which also deals with
9 sealed sources, in particular, brachytherapy. That is part
10 of the written exam. There is also a huge written exam in
11 radiation effects, including carcinogenesis and genetics.
12 It is a multiple choice exam that lasts about six hours.
13 That is in place for Group ^{VI} people, and we look at that.

14 DR. COLLINS: I have only one comment this
15 afternoon on the public perception of our action here. If
16 it should go to reduce our six to four months, we have had a
17 great deal of discussions, but we're talking solely about
18 safety. There is a nasty word I haven't heard mentioned
19 today -- rem, rad, millirem, millirad. That is the danger.
20 If we are so concerned, and we are, it would be well if we
21 gave a little more attention to the magnitude of the
22 problem, because the public perception of about 100 folks
23 gathered from around the country today to discuss their
24 safety, I think they can go home and say, well, I really
25 don't know what the answer is.

1 What is the hazard that we are speaking about, the
2 magnitude of it with regard to our nuclear cardiology, for
3 instance? Through my own experience ~~for~~ observation, there
4 seems to be more hazard in mentioning the fluoroscopy that
5 goes on, then it mentioned the nuclear aspect of
6 cardiology.

7 MR. CUNNINGHAM: I think a lot of people would
8 agree with you on that.

9 I would like, before I try to summarize some
10 things, to just start with the members of the committee and
11 to ask if they want to say anything more about the proposal
12 put forth by the Task Force on four months training for
13 nuclear cardiology and the split -- the divided opinions
14 between those who worked on this task force between the four
15 months and six months training for the remainder of nuclear
16 medicine.

17 Does anyone have any more comments on that? That
18 is one of the issues we will have to act on.

19 (No response.)

20 MR. CUNNINGHAM: No more comments on that.

21 Dr. Woodbury?

22 DR. WOODBURY: I think I have already commented.
23 In an effort to have a separation of qualifications, this
24 opens a Pandora's box.

25 MR. CUNNINGHAM: Let me try to summarize.

1 What I have been able to glean out of this
2 meeting, the first is that there indeed still remain divided
3 opinions about the amount of training necessary to provide
4 adequate radiation protection in the practice of nuclear
5 medicine, whether it is one specialty in nuclear medicine or
6 nuclear medicine in a more broad context.

7 The second thing is that the point at issue seems
8 to center on the patient rather than the radiation
9 protection provided to workers and the public.

10 Granted there are some areas where they can be
11 affected, but the key issue seems to center on the patient,
12 and it has to do with the dividing point between what is
13 clinical practice and what is radiation safety.

14 The example was used here: bad clinical judgment
15 can lead to poor radiation safety.

16 The third point is that many commenters indicated,
17 and much of the committee indicated, that really the
18 number of hours are not the critical issue. The number of
19 hours is a mechanism for a regulatory agency to come to
20 grips with. The critical issue is the quality of the
21 training and the quality of students that come out of these
22 training programs.

23 And ideally, if NRC were to be able to come up
24 with a quality control program, that is, control of the
25 quality assessment program -- I guess I do mean quality

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1 control, control of the quality of training provided to
2 physicians, coupled with some assessment of the physicians'
3 qualifications after they come out of this training program,
4 then, indeed, the number of ^{hours}~~ours~~ of training would become a
5 moot issue.

6 I also come away from this with the opinion that
7 any long-term effects that NRC might try to provide on the
8 quality of medical practice should recognize, or the quality
9 of radiation protection, should recognize that the patterns
10 of medical practice are changing, a shift away from
11 hospitals to private practitioners and that the types of
12 diagnostic and therapeutic procedures that dominate today's
13 medical practice are not necessarily those ^{procedures}~~proceedings~~ that
14 dominate future practice. Therefore, as we change these,
15 and we consider these, we must certainly take the shifting
16 patterns into account.

17 Given these understandings, this is basically what
18 I derive from all that I have heard today.

19 Does somebody want to add to this before I try to
20 say where we should go?

21 (No response.)

22 MR. CUNNINGHAM: All right.

23 The Staff will review the record and try to come
24 up with some proposal that accommodates. The proposal will
25 go to the Commission. We will attempt, under the idea that

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1 we might try to accommodate at least in the short term some
2 of these problems various people have brought forth;
3 however, coupled with that, a relook at how NRC determines
4 qualifications for radiation safety. I want to see, and we
5 may call on the members of our Advisory Committee, or it
6 might be necessary to get some special consultants to see if
7 there is a way to change how we do these evaluations, to
8 bring in the idea of quality control in clinical practice,
9 so we won't be so bound by the number of hours that I
10 believe will continue to be controversial, in part, at
11 least, because it really doesn't address the fundamental
12 problem with which we're dealing.

13 Now the Staff will try to develop something, I
14 just don't know the time yet, but to discuss it with the
15 Staff, something for you to look at on the direction we
16 should be going on training, based on what we have been able
17 to learn and understand today.

18 Does anybody want to add to this?

19 I propose to leave it at this point, unless
20 somebody wants to add something. Dr. Pohost.

21 DR. POHOST: Just one brief comment. I wouldn't
22 count on medicine continuously from then on moving out of
23 the hospital into the outpatient clinic, because similar
24 controls on outpatient clinics can be anticipated in the
25 future. So whatever plans you come up with, I think have

1 to be tempered with the thought that even the outpatient
2 clinic is in line for DRG-type activities.

3 MR. CUNNINGHAM: I can't respond to that.

4 DR. POHOST: You mentioned this is one of the
5 things we learned today.

6 MR. CUNNINGHAM: It's not just today. A number of
7 people have mentioned this. It does seem that there is
8 definitely a shift, whether it continues, I don't know, but
9 there does seem to be a shift that I have heard and that
10 I've read, and I think will continue in the future.

11 Dr. Webster?

12 DR. WEBSTER: When you communicate with the
13 Commission, will you advocate some particular format for the
14 training of these various groups we've been discussing
15 today, when you come to a conclusion, in other words, based
16 on your own examination of the record?

17 MR. CUNNINGHAM: I'd like to examine the record
18 and discuss that with the Staff, before I answer that. I
19 just don't know at this point. Certainly, I must say I am
20 really not expecting that we would all collectively here
21 come to a unanimous opinion about what training should be,
22 but I think we did develop in the course of these
23 deliberations, some things for the Staff -- to provide a
24 basis for the Staff to proceed, when we look a little bit
25 closer at the record that's been developed.

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I think we can draw this meeting to a close.

Before we close, I want to make a couple of more comments, but does anyone have any other subject that they want to bring up, briefly?

(No response.)

MR. CUNNINGHAM: I would like, in closing this meeting, something I should have done at the beginning of the meeting, is note that Dr. Pohost and Dr. Herrera are new members of the Advisory Committee. We do have a practice of rotating committee members periodically. Some members have served a long time. Members are not rotated nearly as often as they should be, but I think it is very appropriate that Dr. Pohost and Dr. Herrera, who has had to leave, are serving on the Committee at ^{this} ~~the~~ same time. Two committee members who are attending these meetings this week are attending for the last time. They are the physician members who have served longest on the Committee, and I want to say that over the years, both these physician members, Dr. Workman and Dr. DeLand, who have been here since 1897 -- oh, Dr. DeLand's gone too -- over these years, both Dr. Workman and Dr. DeLand have certainly been very generous with their time, staff and ^{they are} ~~these~~ people ^{been} ~~been~~ that we've always been able to count on and ~~be~~ able to call on with very strange questions, have been very patient with us and certainly very helpful.

1 And to me personally, I think that they have been
2 very good friends and very helpful to me in some difficult
3 things I have had to do, to come to grips with, in my tenure
4 at the NRC.

5 So on behalf of the NRC, the Commissioners and
6 certainly members of the Materials Staff, and most
7 gratefully from me, I wish to thank you, Joe, and I wish
8 Dr. DeLand were here to thank also. Thank you very much.

9 DR. WORKMAN: It's been our pleasure, I'm sure.
10 Thank you very much.

11 MR. CUNNINGHAM: On that note, unless there are
12 other comments, I would close the meeting.

13 Thank you very much.

14 (Whereupon, at 3:20 p.m., the meeting of the
15 Advisory Committee was adjourned.)

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This is to certify that the attached proceedings before the UNITED STATES NUCLEAR REGULATORY COMMISSION in the matter of:

NAME OF PROCEEDING: ADVISORY COMMITTEE ON THE MEDICAL USES
OF ISOTOPES

DOCKET NO.:

PLACE: BETHESDA, MARYLAND

DATE: FRIDAY, MAY 3, 1985

were held as herein appears, and that this is the original transcript thereof for the file of the United States Nuclear Regulatory Commission.

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DAVID L. HOFFMAN

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