

**Official Transcript of Proceedings**  
**NUCLEAR REGULATORY COMMISSION**

Title:                   Advisory Committee on the Medical  
                              Uses of Isotopes (ACMUII)

Docket Number:       (not applicable)

Location:               Rockville, Maryland

Date:                   Wednesday, April 18, 2001

Work Order No.:       NRC-168

Pages 1-300

**NEAL R. GROSS AND CO., INC.**  
**Court Reporters and Transcribers**  
**1323 Rhode Island Avenue, N.W.**  
**Washington, D.C. 20005**



1 UNITED STATES OF AMERICA

2 NUCLEAR REGULATORY COMMISSION

3 + + + + +

4 ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

5 (ACMUI)

6 + + + + +

7 WEDNESDAY

8 APRIL 18, 2001

9 + + + + +

10 ROCKVILLE, MARYLAND

11 + + + + +

12 The Advisory Committee on the Medical Uses  
13 of Isotopes met at the Nuclear Regulatory Commission,  
14 Two White Flint North, Room T2B3, 11545 Rockville  
15 Pike, at 8:13 a.m., DR. MANUEL CERQUEIRA, Chairman,  
16 presiding.

17 COMMITTEE MEMBERS:

18 DR. MANUEL CERQUEIRA, Chairman

19 DR. NAOMI ALAZRAKI, Member

20 DR. DAVID DIAMOND, Member

21 MR. JOHN GRAHAM, Member

22 MR. TOM HEATON, Member

23 MS. NEKITA HOBSON, Member

24 MS. RUTH MCBURNEY, Member

25 DR. SUBIR NAG, Member

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

COMMITTEE MEMBERS: (cont.)

DR. SALLY SCHWARZ, Member

DR. RICHARD VETTER, Member

DR. JEFFREY WILLIAMSON, Member

MR. JOHN HICKEY, Designated Federal Official

SPECIAL CONSULTANT:

DR. LOUIS WAGNER

PARTICIPATING NRC EMPLOYEES:

DR. ROBERT AYRES, NMSS/IMNS/MSIB

MR. FREDERICK BROWN, NMSS/IMNS/MSIB

DR. DONALD COOL, NMSS/IMNS

MS. CATHERINE HANEY, NMSS/IMNS/RGB

DR. DONNA-BETH HOWE, NMSS/IMNS/MSIB

MR. FREDERICK STURZ, NMSS/IMNS/MSIB

MS. ANGELA WILLIAMSON, NMSS/IMNS/MSIB

MS. LINDA PSYK, NMSS/IMNS/MSIB

PARTICIPATING MEMBERS OF THE PUBLIC:

DR. JEFFREY BRINKER, Society for Cardiac  
Angiography & Interventions

DR. MICHAEL GILLEN, American Association of  
Physicists in Medicine

NUMBER OF MEMBERS OF THE PUBLIC PRESENT: 31

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11

## I-N-D-E-X

<u>AGENDA ITEM</u>	<u>PAGE</u>
Opening Remarks by Chairman Manuel Cerqueira . . .	4
Follow-up to Items from Previous Meeting . . .	11
Status of ACMUI Vacancies . . . . .	16
Status of 10 CFR Part 35/Part 35.75	
Rulemakings . . . . .	26
10 CFR Part 35 Transition and Implementation .	64
Issues	
Recognition of Certification Boards . . . . .	68
Authorization for Brachytherapy Procedures Not	
Covered by FDA Approvals . . . . .	139
Physical Presence Issue for New Brachytherapy .	172
Procedures: Presence of Medical Physicist	
Authorization for Broad Licensees to Utilize .	227
New Brachytherapy Procedures	
Additional Items . . . . .	238
Rejection of Medical Waste by Local Landfills .	254
ACMUI Interactions with Staff . . . . .	274
Self-Evaluation Criteria for ACMUI . . . . .	281
Open Discussion of Next Meeting Dates and . .	292
Agenda Topics	
Summary of Meeting by Dr. Cerqueira . . . . .	294
Adjournment . . . . .	300

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
 1323 RHODE ISLAND AVE., N.W.  
 WASHINGTON, D.C. 20005-3701

P-R-O-C-E-E-D-I-N-G-S

(8:13 a.m.)

CHAIRMAN CERQUEIRA: My name is Dr. Manuel Cerqueira, and I am the Chairman of the ACMUI. My apologies for being late. As a local, I actually had to stop at the hospital this morning before coming here. So it is hard to predict traffic.

But I would like to welcome everyone to the meeting, and again my apologies for starting a little bit late, and I think we can start off by having some opening remarks from John Hickey.

MR. HICKEY: Good morning. I am John Hickey from the Nuclear Regulatory Commission. I am the newly designated Federal Official for the Advisory Committee on Medical Uses of Isotopes. That means that I am the NRC liaison to the Committee.

The committee members have other positions and they are serving in an advisory capacity to NRC, and we certainly appreciate you taking the time to be here. We know that you all have very busy schedules.

This meeting is an open announced meeting. It was announced in the Federal Register on March 16th, and it is open to members of the public for observation. The meeting is being transcribed by Paul over here.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1           So, please speak and identify yourselves  
2           so that it promotes a clear transcription of the  
3           meeting. Everything here is on the public record, and  
4           so keep in mind that everything that you say here is  
5           a matter of public record, and if you get into medial  
6           information, refrain from discussing any medical  
7           information that is not appropriate for disclosure to  
8           the public.

9           I would like to point out that in addition  
10          to the presentations that you will hear today, there  
11          were five written presentations submitted by  
12          organizations for the Committee's information.

13          Copies of those documents are being  
14          distributed to the Committee, and copies will be made  
15          to the public in the back of the room. The documents  
16          were submitted by the Society of Nuclear Medicine, The  
17          American College of Cardiology, The American Society  
18          of Therapeutic Radiology and Oncology, Novoste  
19          Corporation, and the American Association of  
20          Physicists in Medicine.

21          We will refer to those documents at the  
22          time on the agenda when we are discussing the topic  
23          that the document relates to.

24          In addition to the NRC staff members that  
25          will be making presentations, we have Dr. Michael

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701



1 Gillin, from the Medical College of Wisconsin, who  
2 will also make a statement in connection with the  
3 written statement from the American Association of  
4 Physicists in Medicine when we talk about  
5 certification boards at 10:00 a.m.

6 We would also like to thank Dr. Jeffrey  
7 Brinker at the end over here. I'm sorry that this  
8 table is a little crowded. He is an Interventional  
9 Cardiologist from Johns Hopkins University, and he has  
10 accepted our invitation through arrangement with the  
11 American Society for Cardiac Angiography and  
12 Intervention in the American College of Cardiology,  
13 because one of the significant topics that we have  
14 been discussing at these meetings has been  
15 intervascular brachytherapy in cardiology procedures.

16 The function of the ACMUI is to advise NRC  
17 on issues and questions that arise on medical uses of  
18 radioactive material. It provides counsel to the NRC,  
19 but the Committee itself does not determine or direct  
20 the actual decisions of the Commission.

21 The NRC values the opinions of the  
22 Committee very much in making our regulatory  
23 decisions. We are interested in all of the views of  
24 the committee. It is of interest to us when the views  
25 reflect an consensus of the committee, but it is also

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 important that individual views be recorded because  
2 you represent various constituencies and stakeholders.

3 And so sometimes an individual view is as  
4 significant as the view of the committee and NRC  
5 considering a regulatory decision. And when I am done  
6 the Chairman will ask you to go around the table and  
7 introduce yourselves.

8 And it is also my responsibility to review  
9 the issue of potential conflicts of interest in the  
10 participation of the members of the committee for the  
11 various agenda topics.

12 I have determined that the agenda topics  
13 that we will be discussing today are of a general  
14 nature, and there is only one item that is of note,  
15 and that is that the Chairman, Dr. Cerqueira, has  
16 requested that he recuse himself from the discussions  
17 of the American Board of Nuclear Cardiology during the  
18 10 o'clock discussion.

19 So he can sit and listen to the  
20 discussion. Bear with us, Dr. Cerqueira, but it has  
21 been your request that you not actually participate in  
22 the discussion.

23 I would also point out that these periodic  
24 meetings are conducted in a time of change, both on  
25 the part of the committee and the NRC staff, and I

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 would like to introduce to you Angela Williamson,  
2 which I will do in a minute.

3 Many of you have dealt with Angela  
4 Williamson, who is the project manager for the  
5 Committee, and so she has made a lot of the  
6 arrangements causing the meeting to happen today.

7 And you also will see some people that are  
8 making presentations today that you have not seen  
9 before, and that is a reflection where I have been in  
10 this program for about two years, and this is the  
11 first time that I have been the Federal Official for  
12 this meeting, and you will also see some other new  
13 faces as a result of the staff changes at NRC.

14 So we would appreciate it if you would  
15 bear with us as we maintain the valuable function of  
16 these committee meetings in receiving your counsel in  
17 the midst of administrative changes on our part, and  
18 with that, I would turn this back to back to Dr.  
19 Cerqueira.

20 CHAIRMAN CERQUEIRA: Thank you very much,  
21 John. Should we do the introductions of the people  
22 now? Perhaps we could start at this end with Richard,  
23 and have people introduce themselves, and which  
24 stakeholders they represent.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 DR. VETTER: Richard Vetter, from the Mayo  
2 Clinic, and I represent the Radiation Safety  
3 Officers.

4 MS. WAGNER: Lou Wagner, and I am from the  
5 University of Texas, Houston Medical School. I  
6 represent Nuclear Medicine Medical Physicists.

7 MR. WILLIAMSON: I am Jeff Williamson,  
8 from Washington University, in St. Louis, and I  
9 represent Radiation Oncology Physics.

10 DR. SCHWARTZ: I am Sally Schwartz, and I  
11 am also from Washington University in St. Louis, and  
12 I represent Nuclear Pharmacy.

13 DR. NAG: Subir Nag, Radiation Oncologist,  
14 Ohio State University, Columbus.

15 MR. HEATON: Tom Heaton, from FDA, the  
16 Center for Devices on Radiological Health. I am here  
17 on a one-time request for having somebody from the  
18 Center for Devices here rather than the Center for  
19 Drugs.

20 CHAIRMAN CERQUEIRA: Manuel Cerqueira, and  
21 I at Georgetown University Hospital in D.C., and I  
22 represent Nuclear Cardiology.

23 MR. GRAHAM: John Graham, Beaumont  
24 Hospital, Michigan, representing Health Care  
25 Administrators.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 MS. MCBURNEY: I am Ruth McBurney, from  
2 the Texas Department of Health. I am representing the  
3 State Government people.

4 DR. ALAZRAKI: I am Naomi Alazraki, and I  
5 am from Emory University and the VA Medical Center in  
6 Atlanta. I am representing Nuclear Medicine  
7 Physicians.

8 DR. DIAMOND: I am David Diamond, and I am  
9 a Radiation Oncologist from Orlando, Florida, and I  
10 represent the Radiation Oncology community.

11 MS. HOBSON: And I am Nekita Hobson, from  
12 the National Association of Cancer Patients, and I am  
13 the Patient Advocate.

14 DR. BRINKER: I am Jeff Brinker from Johns  
15 Hopkins University, and representing Interventional  
16 Cardiology.

17 CHAIRMAN CERQUEIRA: Thank you very much.  
18 The next item is actually an award of appreciation,  
19 which will be presented by Dr. Donald Cool.

20 DR. COOL: Thank you, Dr. Cerqueira. I am  
21 Donald Cool, and I am the Director of the Division of  
22 Industrial Medical Nuclear Safety, and our  
23 transcriptionist is probably going to have a fit with  
24 me, because in order to properly do a recognition, I  
25 am going to have to walk away from the microphone.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 But we do like to take opportunities when  
2 folks are unfortunately going to have to not be part  
3 of the organization because of the rules and  
4 requirements to provide some recognition, or  
5 appreciation and thanks for much hard work in  
6 activities.

7 So it is with great sadness that I am  
8 going to acknowledge that Dr. Alazraki is not going to  
9 be able to continue with us after this meeting, and to  
10 wish her the very, very best in her continued  
11 activities, and to thank you very much for all of your  
12 support and help with us these last couple of years.

13 DR. ALAZRAKI: Thank you. I might say  
14 that during the years that I have been here, although  
15 there have been a lot of changeovers in staff, Donald  
16 Cool has always been here.

17 (Laughter.)

18 DR. ALAZRAKI: I have always known Donald  
19 Cool.

20 CHAIRMAN CERQUEIRA: We are all going to  
21 be sad to see you go, but we have really appreciated  
22 all your input over the years, and your sort of  
23 reasoned and logical approach to things.

24 DR. ALAZRAKI: Thank you.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 CHAIRMAN CERQUEIRA: I guess we will move  
2 on to the next agenda item, which is the follow-up of  
3 items from previous meetings, and Frederick Brown from  
4 the NRC will be reviewing that for us.

5 MR. BROWN: Good morning. I am Fred  
6 Brown, and what I would like to go over real briefly  
7 is in your briefing books under the tab of November  
8 8th and 9th follow-up.

9 We are going to start a new format of  
10 communication relative to the minutes of meetings.  
11 There are several objectives, and the most important  
12 I hope is that we will more effectively communicate to  
13 you the results of your recommendations to us.

14 This format is consistent with how we  
15 communicate with the other advisory committees that  
16 the Commission utilizes, and it is also a more  
17 effective utilization of our resources.

18 And rather than providing a synopsis of  
19 the entire meeting, we will pull the actual  
20 recommendations of the committee out of the  
21 transcripts of the meeting, and then we will inform  
22 you of how we have utilized your recommendations.

23 So I will quickly go through the  
24 recommendations from the previous meeting. The first

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1       dealt with licensing and reporting for the thesphere  
2       modality.

3               The committee made a recommendation that  
4       we use the 35.400 guidance for brachytherapy. We are  
5       currently developing our final guidance, and we are  
6       going to be very consistent with that recommendation  
7       of the committee.

8               The second dealt with -- actually, it is  
9       classified event reporting, but it really had to do  
10      with the difficulty of finding things on our website,  
11      and the agency currently has a very large effort to  
12      redo the website.

13              We have specifically requested that the  
14      search engine be upgraded consistent with your  
15      recommendations. Unfortunately, I can't make any  
16      promises, but we agree and hope that that is the  
17      result.

18              The third area dealt with 35.75 releases  
19      and associated reporting. I am going to basically  
20      leave that to Cathy Haney. There is a presentation in  
21      a few minutes which will go into greater detail.

22              The fourth recommendation was that the  
23      embryo-fetus reporting requirement rule making not  
24      proceed, or that no additional requirements be  
25      established.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433



1           Since the November meeting the Commission  
2       has determined that that rule making has been  
3       terminated consistent with the recommendations of the  
4       Committee.

5           And then the final thing that was  
6       discussed dealt with granting exemptions to training  
7       for teletherapy physicists, and the process that the  
8       committee recommended to us is going to be adopted,  
9       where we will consult with the chair, Dr. Cerqueira,  
10      directly.

11          And then obviously he would communicate  
12      with the rest of the committee as appropriate. So in  
13      general we found all of the recommendations from the  
14      last meeting very helpful. We appreciated them, and  
15      what you should see in the future is a direct response  
16      in this form. If there are any questions, I would be  
17      happy to. Yes?

18          MR. WILLIAMSON: With regard to the new  
19      medical technologies item, I think the underlying  
20      concern was that there looked like the NRC staff was  
21      making an effort to develop a very detailed  
22      prescriptive set of recommendations for each modality  
23      that we are drawn, and at the particular case at hand,  
24      the thesphere, almost verbatim from the written  
25      instructions from the vendor.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1           And I think that was more of the concern,  
2           and so have more sort of reasonable and less  
3           prescriptive and restrictive criteria for writing  
4           guidance been adopted.

5           MR. HICKEY: I think I am probably a  
6           better one to answer that. The answer is in short  
7           yes, and I think in some of the specific topics you  
8           hear later about FDA, and you will hear some of the  
9           considerations that are going into that.

10          MR. BROWN: I think I would just quickly  
11          add that it is an excellent point that we will  
12          actually be responding to the recommendations as they  
13          are made by the Committee.

14          Hopefully we will be responding to the  
15          underlying issue, too. But the more specificity in  
16          the recommendation, the more direct answer you will  
17          receive.

18          CHAIRMAN CERQUEIRA: Mr. Graham, you had  
19          a question?

20          MR. GRAHAM: John Graham. Just to  
21          comment. Over the past six years, there has been an  
22          extensive discussion about this group receiving  
23          feedback and recognizing that it was only advisory.

24          We were never sure what happened to the  
25          recommendations and so I would commend the staff.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 This is an outstanding summary coming back, and this  
2 is the first time that I have seen it. So, thank you.

3 CHAIRMAN CERQUEIRA: That is a positive  
4 response. Any other questions for Mr. Brown? Okay.  
5 If not, thank you, and thanks, John, for your input.  
6 So actually we are back on schedule. That's good.

7 The next item is the status of the ACMUI  
8 vacancies, and is Angela back?

9 MR. HICKEY: Yes. I introduced you in  
10 your absence.

11 MS. WILLIAMSON: Good morning, everyone.  
12 I will skip the introduction as you all know who I am,  
13 and we will get right to the point here, which is the  
14 status of vacancies on committee.

15 DR. NAG: You might want to get it  
16 focused.

17 CHAIRMAN CERQUEIRA: It is difficult to  
18 see, right. People can go to their handouts, to the  
19 tab marked Status of ACMUI vacancies. We actually  
20 have the slides on there.

21 MS. WILLIAMSON: Okay. We have a couple  
22 of vacancies, or actually one is an actual vacancy,  
23 and one is a vacancy after this meeting. The one that  
24 will be the vacancy after this meeting is the Nuclear

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 Medicine position that Dr. Alazraki is currently  
2 holding.

3 We forwarded a staff paper, called SECY  
4 00-0036 to the Commission, and we are awaiting for  
5 applications on this particular vacancy. I wanted to  
6 note though that there has already been progress made  
7 on this. That the call for nominations to advertise  
8 this position has been forwarded to the Federal  
9 Register.

10 And in a few days or so we will know what  
11 that FR is. So we are progressing nicely on that.  
12 All we will have to do after the call for nominations  
13 is to get the nominations in and form a screening  
14 panel. That is the status as of that as of now.

15 CHAIRMAN CERQUEIRA: And what is the time  
16 line on that, Angela? I mean, basically, the Federal  
17 Register notice will be published when?

18 MS. WILLIAMSON: By next week, it should  
19 be published.

20 CHAIRMAN CERQUEIRA: And what is the  
21 deadline for the professional medical society  
22 submitting nominations?

23 MS. WILLIAMSON: 60 days after the  
24 publication of the Federal Register notice.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 CHAIRMAN CERQUEIRA: So hopefully by the  
2 next meeting in November, I guess, we should have that  
3 position filled?

4 MS. WILLIAMSON: Well, I don't know that  
5 we will have the position filled, but we will at least  
6 have applications from people, and we will be able to  
7 begin forming the screening panel. But I doubt that  
8 we will actually have it filled.

9 MR. WILLIAMSON: What is the average  
10 length of time after the close of, I guess, the  
11 nominating period for the position to be -- for the  
12 person to be selected?

13 MS. WILLIAMSON: About 30 to 60 days,  
14 because we have to get permission from the Commission  
15 for the screening panel -- from one of the people that  
16 we need to form the screening panel, which is an  
17 outside Federal employee.

18 And the Commission has to actually approve  
19 that person. So we can't just go out and pick  
20 someone. So after the Commission has approved that  
21 person, then we are able to form the screening panel.

22 CHAIRMAN CERQUEIRA: But could any of that  
23 -- I mean, we are obviously going to wait for the  
24 publication and submission of applicants, but is there  
25 anything that could be done to sort of shorten the

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 process of that appointment? Can that be made  
2 independent of the submission of nominations?

3 MS. WILLIAMSON: I don't think so. No, we  
4 have to -- it is commission driven, but we do have to  
5 get their permission prior to a lot of -- the staff  
6 has to get their permission prior to its action, and  
7 we can't really jump the gun on that sort of thing.

8 All we can tell you is that it should be  
9 published soon, and to be alert and aware that it is  
10 going to be published, and as soon as possible. I  
11 mean, already have your people lined up that you have  
12 in mind, and as soon as it hits the presses, send  
13 those applications in.

14 CHAIRMAN CERQUEIRA: Right. Now, they  
15 will be sent in, but they you have 60 days, and then  
16 the Commissioners I guess have to appoint a committee.  
17 Now, is the committee the ACMUI or is it the --

18 MS. WILLIAMSON: No, no. The committee is  
19 a screening panel --

20 CHAIRMAN CERQUEIRA: Of NRC staff people?

21 MS. WILLIAMSON: -- of NRC staff and an  
22 outside Federal employee.

23 CHAIRMAN CERQUEIRA: Okay. So I guess the  
24 question I was asking is why couldn't that be done  
25 ahead of time in anticipation and in 60 days all of

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 the applicants will be in so that at the 60 day time  
2 point, we could begin the process?

3 I guess that the Committee is recommending  
4 that we initiate that, because if we wait for 60 days,  
5 and then you initiate the process performing the  
6 screening committee, it is going to add to the delay.

7 MS. WILLIAMSON: Right. What about  
8 literally waiting until the 60th day? What we are  
9 doing is that in the meantime while we are waiting on  
10 the applications from the perspective or from the  
11 candidates, we can begin identifying the outside  
12 Federal employee. We can do that.

13 CHAIRMAN CERQUEIRA: I guess what the  
14 committee is recommending is that that process be  
15 initiated so that at the end of the 60 days we would  
16 already have that group formed.

17 MS. WILLIAMSON: Right. And normally that  
18 is what we do. That's the way it is handled anyway.  
19 Sometimes as you might well imagine, it can be a bit  
20 of a logistical challenge -- and I will get right to  
21 you, sir.

22 But it can be a bit of a logistical  
23 challenge to find that person, to mesh the schedules,  
24 and that sort of thing. It is just logistics, but we  
25 don't literally wait until the 60th day before we even

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 begin the process of finding the other person that we  
2 need to form the panel.

3 CHAIRMAN CERQUEIRA: Mr. Wagner.

4 MR. WAGNER: I would just like to point  
5 out that this has been an ongoing issue in my six  
6 years of service on this committee, and there has been  
7 recommendations in the past that the NRC take a  
8 farsighted look at this.

9 And when they know that a term is going to  
10 expire, then a year or so, or maybe a year-and-a-half  
11 before, the process should begin to fill the new  
12 position because you know the person is going to be  
13 rotating off, and it is going to be vacant.

14 That recommendation has been made by this  
15 committee in the past, and it has not been followed up  
16 on, and so now that we have this new policy of  
17 following up on these recommendations, I think it  
18 would be nice if the NRC could tell us whether or not  
19 they are going to try to rearrange this so that we can  
20 have these positions filled at the time at which they  
21 are vacant.

22 We have had many times during the past six  
23 years wherein there has been vacancies on this  
24 committee and the committee has been dwindled down to  
25 a few numbers, to a few of the voting members.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701



1           So, again I would like to repeat that I  
2           think there is some history there which can be brought  
3           back and looked at again.

4           MR. HICKEY: Yes. This is John Hickey,  
5           and that makes sense to me, and we can take that as an  
6           action item.

7           CHAIRMAN CERQUEIRA: Good. Okay.

8           MR. WILLIAMSON: Should we make a formal  
9           recommendation?

10          CHAIRMAN CERQUEIRA: Yes. We would have  
11          to make a motion.

12          MR. WILLIAMSON: Yes. I would move that  
13          the ACMUI recommend to the commission that the  
14          procedure for recruiting and appointing ACMUI members  
15          begin as soon as the vacancy becomes known, and not at  
16          the time of the actual vacancy.

17          CHAIRMAN CERQUEIRA: Are there any seconds  
18          on that?

19          DR. DIAMOND: I would second that, Jeff.

20          CHAIRMAN CERQUEIRA: And any discussion?  
21          Mr. Graham.

22          MR. GRAHAM: Just a point of  
23          clarification, because we did discuss this at two  
24          meetings back, and my understanding is that my

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 appointment expires in October, and you are going to  
2 hear about the recruitment of my replacement today.

3 So they have shifted this up a full year  
4 earlier than what was done in the past. So I think  
5 they are moving in the right direction.

6 CHAIRMAN CERQUEIRA: Any further  
7 discussion?

8 (No audible response.)

9 CHAIRMAN CERQUEIRA: I would call for a  
10 vote. All in favor?

11 (A chorus of ayes.)

12 CHAIRMAN CERQUEIRA: Opposed?

13 (No audible response.)

14 CHAIRMAN CERQUEIRA: All right. Good.  
15 Thank you. Angela.

16 MS. WILLIAMSON: And as Mr. Graham has  
17 already said, we are working to determine beyond the  
18 Health Care Administrator vacancy that will appear  
19 after his departure.

20 And what we have done towards that end is  
21 that we have already forwarded our papers up to the  
22 commission, and we have already forwarded a paper up  
23 to a point of the screening panel member, and you will  
24 be happy to know that even though my last bullet says

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1       awaiting commission approval of screening panel  
2       candidate, we have that person already approved.

3               So as of May, we will be forming a  
4       screening panel for both, the Health Care  
5       Administrator vacancy, and the Nuclear Medicine  
6       Physician vacancy.

7               CHAIRMAN CERQUEIRA: That's correct. I  
8       guess that answers our earlier question, and that's  
9       good. Great.

10              MS. WILLIAMSON: Now, for the Medical  
11       Physics and Nuclear Medicine vacancy, again we  
12       forwarded our papers. You know what? I mis-spoke.  
13       We have a screening panel candidate for the Medical  
14       Physics vacancy and the Health Care Administrator  
15       vacancy.

16              For Dr. Alazraki's position, we just got  
17       a notice that the Federal Register notice will be  
18       published soon. So I mis-spoke on that. But it is  
19       the Medical Physics and Health Care Administrator  
20       screening panels that will be formed in May.

21              DR. ALAZRAKI: Do these screening panels  
22       have to be different; one screening panel for each  
23       position? Can't they be lumped together?

24              MS. WILLIAMSON: Well, not really, because  
25       the screening panel always consists of an outside

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 Federal employee that is skilled in the vacancy to be  
2 filled.

3 So, for instance, for the health care  
4 administrator screening panel, it consists of three  
5 NRC employees, and those employees are almost always  
6 the same.

7 But the fourth person, the outside Federal  
8 employee, is a specialist in health care  
9 administration. So we can't really lump them all  
10 together. We have all the applications in front of us  
11 and we have to screen the applications with that  
12 specialist there to guide us. Any further questions?  
13 If not, thank you. Oh, I'm sorry.

14 DR. ALAZRAKI: Can I be the outside panel  
15 representative for screening for a Nuclear Medicine  
16 position?

17 MS. WILLIAMSON: Sure. I mean, the  
18 commission has to approve it.

19 DR. ALAZRAKI: Well, that would seem to be  
20 a natural kind of thing to do, is to take the person  
21 who is going off and make that person the panel  
22 screener.

23 MS. WILLIAMSON: But we have to do it  
24 formally. We have to solicit or we have to contact  
25 people and do it through formal channels. We can't

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 just say, okay, definitely you will be the one to sit  
2 on the screening panel.

3 MR. WILLIAMSON: You have to be a Federal  
4 employee.

5 MS. WILLIAMSON: yes.

6 DR. ALAZRAKI: Which I am.

7 CHAIRMAN CERQUEIRA: Which she is.

8 MR. WILLIAMSON: And I guess we are  
9 special government employees, and so I supposed that  
10 we could be involved in the selection of our  
11 successors before we rotate off.

12 DR. ALAZRAKI: That's right.

13 MS. WILLIAMSON: Okay. Thank you.

14 CHAIRMAN CERQUEIRA: Any further questions  
15 for Angela? If not, thank you very much, Angela. The  
16 next item is one of great interest to everyone and  
17 that is the status of the 10 CFR Part 35, 35.75 rule  
18 making.

19 And, Cathy Haney, who is well known to all  
20 the committee members, will be giving us an update.  
21 Cathy.

22 MS. HANEY: Good morning. Thank you. It  
23 is rather interesting to be on this side of the table  
24 than back in the audience now. I am going to talk to  
25 you a little bit about where we are on Part 35 rule

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 making as a whole, and also talk about the petition,  
2 the status of the petition that the Society of Nuclear  
3 Medicine and the American College of Nuclear  
4 Physicians set in.

5 And then as time permits, I want to talk  
6 to you a little bit about where we are on the  
7 following rule making that had to do with notification  
8 relative to 35.75.

9 But before I go into all of that, I just  
10 wanted to follow up on one thing that I think Fred had  
11 said. When he referred to the embryo-fetus rule  
12 making as being terminated, that is not the rule  
13 making that is in 35 right now, the revised 35.

14 That was a rule making that was going to  
15 take requirements for embryo-fetus reporting beyond  
16 the medical arena. So I just want to make sure that  
17 you realize that that requirement did stay in Part 35.

18 All right. As far as where we are on Part  
19 35 right now, when I last spoke with you, I told you  
20 that the next step was to get the package to the  
21 Office of Management and Budget to get their approval  
22 on the record in keeping in reporting requirements.

23 That package did go to OMB the week of  
24 March 12th, and it is currently under review by OMB,  
25 and by March 16th, NRC issued a Federal Register

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 notice just indicating that the document was with OMB,  
2 and if any individuals had any comments that they  
3 could provide OMB.

4 The comment period closed on April 16th,  
5 just this week. I only know of three letters that  
6 have gone to OMB so far. There could be others, but  
7 that's as much as I know at this point.

8 And where we are right now with the  
9 process is the comment period has closed. So we are  
10 kind of in a wait position right now for OMB to come  
11 back to us and either say you have our approval, or to  
12 ask for additional clarification on some of the items.

13 Typically, OMB likes to work towards a 60  
14 day time period for giving approval, and that is from  
15 the time that they receive it. So that is back the  
16 week of March 12th.

17 We have had rules that have gone beyond 60  
18 days and so I don't want you to think that on the 60th  
19 day that we are anticipating to get the approval. But  
20 at least that is the time period that OMB is working  
21 toward.

22 I have not personally heard from OMB since  
23 the week that we sent it down, and that is the week  
24 after we sent it down to them.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 CHAIRMAN CERQUEIRA: So, Cathy, that would  
2 put it around May 12th then is the period that we  
3 expect that they would make a final decision; is that  
4 correct?

5 MS. HANEY: I think that is the earliest.  
6 I mean, realistically, I think it is going to probably  
7 be beyond that 60 days.

8 CHAIRMAN CERQUEIRA: So they try to do it  
9 within 60 days, but is there a limit as to how long it  
10 could be?

11 MS. HANEY: No. I think just from what I  
12 have been able to gather that is one of their internal  
13 goals.

14 CHAIRMAN CERQUEIRA: And with the three  
15 comments were there any specific issues raised in  
16 those comments, or are we not aware of what was  
17 provided?

18 MS. WILLIAMSON: No, there were -- and  
19 again this is what I -- I have limited knowledge at  
20 this point about what they have. But the American  
21 Association of Physicists in Medicine sent in a  
22 letter, and it had to do with the comments on the  
23 training and experience requirements and  
24 certification, which is one of the things that is  
25 discussed later at this meeting.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701



1           Then the Society of Nuclear Medicine, and  
2           the American College of Nuclear Physicians sent in a  
3           letter relative to the actual burden of implementing  
4           the rule.

5           And then I just learned this morning that  
6           this was ASTRO and ABR -- ACR -- sent in a letter  
7           providing comments on the rule, and also supporting  
8           the AAPM letter. So that is all that I know at this  
9           point.

10           MR. WAGNER: Thank you.

11           MS. HANEY: I did list the websites for  
12           the rule and the OMB package up on the website in case  
13           any of you have not seen the latest version of the  
14           rule, and that's where it is. And I am going to take  
15           a two minute break.

16           (Brief Pause.)

17           MS. HANEY: All right. The other thing  
18           that I just wanted to follow up with is a petition.  
19           I am aware that information on this petition was  
20           provided to the ACMUI. It was -- we received a  
21           petition from the Society of Nuclear Medicine, ACMP,  
22           on January 3rd.

23           And in-part it asked us to revoke all of  
24           Part 35, except for specifically identified  
25           requirements. Most of those had to do with training

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 and experience, and also a requirement for an exam.  
2 And in the information that you were provided it goes  
3 into a more detailed analysis of what they asked for.  
4 We did look --

5 DR. NAG: Could you explain what is meant  
6 by that?

7 MS. HANEY: Well, they asked specifically  
8 that there were requirements in Part 35 that were not  
9 needed for safety given the risk associated with the  
10 use of material in -- it was primarily focused on  
11 diagnostic nuclear medicine. I guess that is really  
12 fair to say.

13 So the comment was specific to that, and  
14 as I said, I think you have copies of all of that  
15 information. I do want you to know that on April 13th  
16 that the Commission denied the petition for the  
17 following reasons, and I am not going to -- I will  
18 just summarize them real quickly.

19 We did go through this rule making process  
20 with an enhanced stakeholder and public participation.  
21 The comments that SNM and ACNP provided in their  
22 petition, they had many opportunities to provide those  
23 to us before, and they have.

24 And also the petition did not provide any  
25 new significant information. I'm sorry, I've had this

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 cold for a week, and so I am actually better than what  
2 I was.

3 So based on that, we did deny it. The  
4 petitioner was notified of the denial on Monday, and  
5 I suspect that it will be published in the Federal  
6 Register either tomorrow or Friday. I checked this  
7 morning and it was not in this morning's publication.

8 CHAIRMAN CERQUEIRA: Now, Cathy, the  
9 petition that was sent by the SNM and ACNP to the OMB,  
10 I guess that would address the same issue. Now, is  
11 there any way that the Commissioner's rule making  
12 could be sent to the OMB reflecting the Commission's  
13 opinion?

14 MS. HANEY: Well, I guess a couple of  
15 things. One, it was not a petition that the SNM and  
16 ACNP sent to OMB. It was just a letter of comment.  
17 But, yes, we will provide OMB with a copy of our  
18 denial and the reasons for it.

19 And the next thing, and I am only going to  
20 talk two more minutes, and then you all can give me  
21 information, is that if you go back to a year or so  
22 ago when we got the final okay from the Commission to  
23 go ahead with finalizing Part 35, they did ask that we  
24 add a new record keeping requirement, 2 Part 35, and  
25 this was going to be done as a separate rule making.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1           The words that you see on the view graph  
2 really comes -- well, comes straight from the staff  
3 requirements memorandum that we received. And the key  
4 here is to realize that this reporting requirement  
5 would cover releases that were in accordance with Part  
6 35, as well as those that were not in accordance with  
7 Part 35.

8           So it is a very broad record-keeping  
9 reporting requirement. We did discuss this a little  
10 bit at the last meeting, and we will get into -- I  
11 will just refresh your memory with the recommendations  
12 in a few minutes.

13           But I want you to realize that this will  
14 cover -- that this rule making would encompass cases  
15 where the licensee believes that the release may have  
16 been incorrect, or that the licensee learns through  
17 voluntary means the patient didn't follow their  
18 directions.

19           In other words, when the patient comes  
20 back for a follow-up visit, he says, oh, you know, I  
21 told you that I was going to my mountain retreat. I  
22 didn't. I got on a plane and flew to Hawaii.

23           And then this would cause the licensee to  
24 take some type of action based on that. However, in  
25 line with all of that, we are not changing our

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 position that we expect the licensee to follow up and  
2 enforce patient's compliance with the licensee's  
3 instructions.

4 And that is a very key thing, and we are  
5 going to work these two statements into the statements  
6 of consideration for the rule. At the last meeting,  
7 when we did discuss this, and it was given maybe --  
8 oh, I think we have 5 or 10 minutes to discuss it, we  
9 had talked about how ACMUI had made a recommendation.

10 And this recommendation focused that we  
11 should be -- that the requirement that would go into  
12 the rule would only be based on the situation where  
13 there was an error made in the release of the patient,  
14 or an error made in the delivery of the instructions  
15 to the patients.

16 So the Committee as a whole is trying to  
17 focus this reporting requirement, as compared to  
18 leaving it very broad as the commission had directed  
19 the staff to do.

20 So we have been trying to work with the  
21 staff requirements memorandum, and also with the  
22 direction that the ACMUI gave us, but we are at a  
23 point now where we need a little bit more information  
24 from the committee, and that's why I asked for a few  
25 minutes to meet with you today.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1           What I pose on the next two view graphs  
2           are five questions that I would like the committee to  
3           try to give me some answers on, as far as this was the  
4           order I had envisioned them being discussed in.

5           But if for the committee's purposes it  
6           chooses to kind of bounce around a little bit more,  
7           that's fine, too. And I guess I will just turn it  
8           back to you, Dr. Cerqueira, and you can -- maybe I can  
9           get all the questions on the same.

10           CHAIRMAN CERQUEIRA: Okay. Well, why  
11           don't we go down in order. I guess the first question  
12           is what are the implications requiring reporting of  
13           all events where an individual receives a dose greater  
14           than 50 mSv 5 rem from a released patient. Any  
15           comments for Cathy on that?

16           MS. HANEY: This would be really if we  
17           wrote the rule the way the commission directed us to,  
18           and to just report everything, how are you going to  
19           have to change your process? What is the impact on  
20           your day to day operations?

21           CHAIRMAN CERQUEIRA: Dr. Wagner.

22           MR. WAGNER: Well, I think there are two  
23           things right off the bat that I can think of that have  
24           to be considered. The first is the fact that if  
25           someone does receive more than 5 rems, then I fully

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 sympathize with the idea that we ought to know the  
2 information, and we ought to know what generated that,  
3 and the causes that surrounded that.

4 The purpose of gaining and obtaining that  
5 information is to find out how prevalent that may be,  
6 and whether or not there is an issue that should be  
7 addressed with regard to the safety of the public, and  
8 I think that is a very important issue.

9 But the second thing is that in reporting  
10 such things in this case, and in the way that it is  
11 currently suggested by the Commission, the hospital or  
12 the facility that released a patient is at no fault  
13 for anything that has occurred.

14 And yet the publicity and the  
15 repercussions of such an event on the facility could  
16 be very negative. And that is a negative downside to  
17 this whole issue.

18 So then the issue, I think, would be this.  
19 Would there be anonymity granted to the facility with  
20 regard to this, and therefore not generate any public  
21 notice towards the facility because the facility has  
22 not done anything wrong, or committed any error.

23 And I think that is a concern that we all  
24 share with regard to that kind of publicity. So I

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 think that these are the two sides that we have to  
2 look at, and that would be my issue.

3 CHAIRMAN CERQUEIRA: Okay. Dr.  
4 Williamson.

5 MR. WILLIAMSON: Well, I echo everything  
6 that Lou mentioned, but there is another concern, too,  
7 that occurs to me. And that is the fact, I think,  
8 that this rule would place the provider of care in a  
9 position to have to act upon what is essentially  
10 hearsay evidence that the institution would become  
11 responsible for, and in a sense, for investigating  
12 this incident and acquiring information to build a  
13 case of yes or no, this happened.

14 And the institution obviously does not  
15 have the right to conduct such an investigation, and  
16 does not access to appropriate information, and I  
17 think the risks as Lou mentioned are fairly great.

18 At the very least what would happen, even  
19 if anonymity is granted to the institution, is that  
20 the patient would be subjected to a fairly intrusive  
21 investigation.

22 And I think that this would put  
23 institutions into a real dilemma of do we report to  
24 NRC based upon this sort of hearsay, very  
25 circumstantial kind of evidence that this may have

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701



1 happened, and subject a patient to this kind of  
2 intrusive investigation, thereby interfering with the  
3 patient-physician relationship.

4 Or does the institution take upon itself  
5 the obligation to investigate this more thoroughly to  
6 determine whether that is necessary, and we do not  
7 have the mandate as providers of care to do this kind  
8 of investigation for events that are beyond our  
9 control. So that is my main concern.

10 CHAIRMAN CERQUEIRA: So, Cathy, I guess if  
11 it is intrusive, and there is a question of anonymity  
12 for the institution, did the commissioners deal with  
13 these specific issues, and what was their response?

14 MS. HANEY: I don't know that those issues  
15 have been raised to the Commission, and that's when  
16 they were developing the SRM, and I think that's one  
17 of the reasons that I wanted to ask the question here.

18 CHAIRMAN CERQUEIRA: Well, I think the  
19 Committee has been pretty straightforward on this one,  
20 you know, with multiple discussions in presentations  
21 to the Commissioners.

22 MS. HANEY: Well, let me answer, too, that  
23 if we were -- that besides those two things, if we put  
24 this into effect, do you think that the licensees  
25 would be less reluctant or less willing to release

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 patients under 35-75 when they could under normal  
2 practice?

3 CHAIRMAN CERQUEIRA: Dr. Nag.

4 DR. NAG: Yes, I think -- well, I echo  
5 both Dr. Wagner and Dr. Williamson, and in addition,  
6 a lot of these calculations would be very time  
7 consuming and would only be an estimate.

8 And those estimates would be far greater  
9 than what the actual number would be. For example,  
10 you can estimate whether they are going to be 10 feet  
11 or a hundred feet, or 10 feet, or one foot away. And  
12 the exposure there is a hundred times different.

13 So the actual number on any estimate would  
14 be very huge, and therefore whatever number you get  
15 may not be a reliable number at all.

16 And based on all the uncertainties and  
17 based on the manpower that we would have to use, I  
18 would become much more comparative, and I would say  
19 that if the patient leaves the hospital.

20 CHAIRMAN CERQUEIRA: Okay. Ruth, and then  
21 Naomi.

22 MS. MCBURNEY: I assume that all of these  
23 would be coming in as complaints, or I don't know how  
24 you would get that information that a person had  
25 received more than 5 rem.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 But certainly I know that the -- and as  
2 was mentioned, it is going to be intrusive to have to  
3 investigate each of these if they are coming in as  
4 complaints.

5 And it is going to be resource intensive  
6 for the compliance folks in NRC and the States if they  
7 have to investigate each of those, even if there was  
8 not an error on the part of the licensee, or if it was  
9 the patient not following directions and that sort of  
10 thing, and then the dose reconstruction, because of --  
11 well, it would be estimates at best.

12 CHAIRMAN CERQUEIRA: Okay. Naomi.

13 DR. ALAZRAKI: It is totally unreasonable  
14 in truth, and undoable. It is not doable, and that's  
15 why people would do what Dr. Nag suggests; is just not  
16 release patients, which is contrary to the intent of  
17 that provision.

18 The only way that a provider could know  
19 what the dose to some other member of the public from  
20 a patient release would be to document, minute-by-  
21 minute, who was in the environment of the patient 24  
22 hours, 7 days, or whatever.

23 So the only thing that is reasonable is  
24 what I think has been specified, are the directions

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1       that the provider must give to the patient in terms of  
2       the precautionary measures that are reasonable.

3               But documenting that in his or her home  
4       that the patient actually followed those directions is  
5       virtually impossible. So I don't know how anyone  
6       would ever know that someone received an excessive  
7       exposure, and there is no enforcing that in any  
8       reasonable manner.

9               CHAIRMAN CERQUEIRA: Richard.

10              DR. VETTER: Two questions. I would like  
11       an answer to the first one before I ask the second if  
12       you please. Is there any reason to believe that these  
13       kinds of events are occurring?

14              MS. HANEY: We have had some enforcement  
15       cases where licensees did not consider 35-75 when they  
16       were releasing patients. One was actually a blind  
17       study, and in that case I believe the member of the  
18       public got an estimated 400 millirems, and so they  
19       were not at the 5 rem limit.

20              So there really isn't the reason for the  
21       high limit, but there are some reasons, like one or  
22       two. So, not a lot. And which may indicate that some  
23       licensees are not even considering 35-75.

24              CHAIRMAN CERQUEIRA: So, Cathy, your last  
25       question of what are the number of reports expected

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 per year from your estimates, it has been what, one in  
2 how many years?

3 MS. HANEY: Probably the history of where  
4 we have records that we can go back and look at it,  
5 and the question there is -- well, I would use the  
6 number -- well, we would have to do a reg analysis  
7 associated with this role.

8 And we need to use a number in that reg  
9 analysis, and that question is there because if you  
10 collectively from having talked and knowing what goes  
11 on in the world, know of maybe some instances where  
12 this is happening, and people are not telling us, or  
13 it is not reaching the 500 rem -- millirem limit, or  
14 whatever, is there a number other than one that I  
15 should be using.

16 CHAIRMAN CERQUEIRA: So what event which  
17 didn't really meet the 5 rem limit in the recorded  
18 history, and so it seems like the numbers are fairly  
19 low, and it is quite an intrusive rule to put into it.  
20 Richard, your second question.

21 DR. VETTER: My follow-up question or  
22 remark is I think or I wonder if we aren't directing  
23 our effort to the wrong place. That is, if we don't  
24 believe -- and we have no evidence to suggest that

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 members of the public are receiving these kinds of  
2 doses, then that is not the issue.

3 The issue based on your enforcement  
4 history is hospitals that are not following the rule,  
5 and so what we should be focusing on is self-reporting  
6 of errors discovered in the release of patients.

7 If a hospital didn't follow the rule  
8 correctly, then that should be reported, rather than  
9 trying to come up with a general rule that all events  
10 earned that anyway. But if a patient didn't follow  
11 our instructions, it is beyond our control as well.

12 So I wonder if the effort should not be  
13 directed toward compliance with the rule, rather than  
14 trying to look at what is happening to the public.

15 MS. HANEY: Okay. I mean, that's a good  
16 comment.

17 CHAIRMAN CERQUEIRA: David, did you have  
18 any comments? We will try to get comments from the  
19 people who have not commented and then we will come  
20 back for any other comments.

21 DR. DIAMOND: Yes, I could not agree more.  
22 The only way to get an objective measure of these  
23 doses is to go and tag every member of the person's  
24 family, their household pets, the people that they  
25 ride the subway with, and so forth.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1           And therefore from first principles, it is  
2           an unworkable and unenforceable scenario that we are  
3           dealing with. I agree with Richard, in that the focus  
4           of course should be placed upon appropriately  
5           maintaining and ensuring that the appropriate release  
6           criteria of the patient is met, and of course that the  
7           health care providers have thoroughly reviewed with  
8           the patients the appropriate radiation safety  
9           considerations for the different procedures.

10           CHAIRMAN CERQUEIRA: Sally, did you have  
11           any comments?

12           DR. SCHWARTZ: Actually, just that I think  
13           that the regulation has to focus on the institution,  
14           in terms of guidelines for the use of the patients,  
15           and possibly making sure that the patients sign that  
16           acceptable criterion have been delivered to them, and  
17           sign the form.

18           I mean, essentially that the licensee has  
19           documented that things have been done properly.  
20           Beyond that, you really can do nothing, because there  
21           is no way to track the population in an accurate  
22           manner.

23           CHAIRMAN CERQUEIRA: And, Nekita, as a  
24           patient advocate?

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 MS. HOBSON: I really can't see how the  
2 more prescriptive rule would help the patient, and in  
3 fact it might harm the patient in the sense that it  
4 could, as Dr. Nag suggests, patients would just be  
5 held in the hospital longer, and it is going to  
6 increase the costs of their care.

7 And it is going to keep them away from  
8 their family, and their more comfortable environment  
9 of home, and so unless I can see some benefit to the  
10 patient, I would agree that the focus should be on the  
11 institutional compliance with release standards,  
12 whatever those are.

13 CHAIRMAN CERQUEIRA: And so the comments  
14 that we have gotten are that it is impossible to  
15 implement, unworkable, unenforceable, and it is  
16 intrusive to the patient. It will probably provide  
17 inappropriate publicity to the institution, and  
18 anonymity for the institution has been requested.

19 It is going to be an inaccurate estimate  
20 of the dose, and it is going to be impossible to  
21 calculate it, and it is going to be very resource  
22 intensive, and the recommendations are more to  
23 basically look at the institutional compliance with  
24 the instructions.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701



1           So that is the general comments. Cathy,  
2           do you want to comment before we go around for a  
3           second time?

4           MS. HANEY: Well, I would just ask the  
5           question of whether -- and just as a follow-up to what  
6           Nekita said, is that from the standpoint of the  
7           general population though, as far as maybe the patient  
8           might not have more confidence, or would the patient  
9           have more confidence in knowing that if the licensee  
10          made an error that they would have to make a report to  
11          NRC or to the State, to the regulatory body, and does  
12          that add a level of comfort there for that patient, as  
13          well for the patient's family.

14          MS. HOBSON: I think most patients are  
15          totally unaware of the regulatory scheme that they are  
16          being treated under. I don't think it would make any  
17          difference. Honestly, I don't think patients have a  
18          clue as to the regulations that are there to protect  
19          the patient.

20          MS. HANEY: Okay.

21          CHAIRMAN CERQUEIRA: Okay. Lou.

22          MR. WAGNER: I have just one comment. I  
23          think the anonymity would also go towards the patient,  
24          and not just the institution. There is a patient  
25          confidentiality factor, too.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1           In addition, I think that I would like to  
2           just comment that the Nuclear Regulatory Commission is  
3           in a rut. I think you have to get out of the box.  
4           You are looking at numbers, and you are asking people  
5           to generate numbers.

6           And if it is 4.999, you are okay. But if  
7           it is 5.001, you're not. And we have this number that  
8           we generate, and obviously we said you can't generate  
9           a number. It is impossible to generate a number.

10          What the NRC should be focusing on is  
11          really safety issues. Now, one suggestion for though,  
12          although I don't think it is workable either, is if a  
13          facility becomes aware that a patient blatantly  
14          violated an instruction, this is really a public  
15          safety issue that the NRC would like to know about.

16          And in that sense it would be reasonable  
17          for them to know that. The problem is getting  
18          information, regardless of what the doses are. Let's  
19          say the patient breast-fed and was told not to. I  
20          mean, that is obviously a violation of instructions,  
21          or something of that nature.

22          And that could have led to an unwanted or  
23          untoward exposure, and that information would be  
24          useful. But the problem is reporting that. That's  
25          the whole problem, is that you can't keep anonymity

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 for the patient, and you can't keep anonymity for the  
2 facility, even though the facility did nothing wrong.

3 So it is a huge problem, and all these  
4 things have to be protected with regard to this  
5 reporting process, and the Commission and the NRC I  
6 think should try to formulate these rules with those  
7 aspects and issues in mind.

8 CHAIRMAN CERQUEIRA: Jeffrey.

9 MR. WILLIAMSON: I think if the Commission  
10 is really concerned about this, the only thing they  
11 could do -- and I don't think this is workable either,  
12 is to create a law that basically requires the patient  
13 to follow the rules.

14 And that if they don't, they have to  
15 report it to the NRC. I mean, that's what you are  
16 asking. That clearly would also provide or be a major  
17 problem, too. It would probably frighten patients,  
18 and eliminate for some of them the possibility of  
19 getting needed health care.

20 DR. DIAMOND: Lou, should we go and arrest  
21 the lady that we find out is breast feeding? I'm  
22 serious. This is exactly as one follows the logic,  
23 one continues to see how unworkable it is. What do we  
24 do? Do we arrest her or do we physically restrain  
25 her?

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 Don't write a rule if there is no method  
2 of enforcing it, or turning it into a logical  
3 conclusion.

4 MR. WAGNER: I don't think this is a rule  
5 though. This is a matter of reporting for information  
6 purposes for the NRC to determine whether or not any  
7 changes in regulations or rules might be necessary as  
8 a result of incidences that expose the public.

9 But I don't think any precedent has been  
10 set, and I don't think there is any data out there  
11 that says there is really a concern that this  
12 reporting criteria really has to be implemented at  
13 all.

14 MR. WILLIAMSON: I concur with that.

15 CHAIRMAN CERQUEIRA: John, and then Dr.  
16 Nag.

17 MR. GRAHAM: I would propose that the  
18 ACMUI reaffirm its recommendation of November 8th and  
19 9th of 2000. We discussed this at length, and it was  
20 at risk informed reporting that a limit of 5 rem  
21 should be limited to a reporting of errors made in the  
22 release of the patient, a reporting of errors made in  
23 the delivery of instructions.

24 Those are the things under the control of  
25 the provider. That is a feedback, Lou, and you can

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 improve the system and the process if you get feedback  
2 on those errors. Other than that, I don't think it is  
3 productive.

4 CHAIRMAN CERQUEIRA: Dr. Nag.

5 DR. NAG: I think a very practical issue  
6 would be to make sure that in addition to explaining  
7 the precautions that should be taken, we have a  
8 written -- you know, we note that some places do have  
9 a written document that is sent to the patient, but  
10 others may not.

11 And we have it that each patient reads a  
12 written document being given to the patient, with a  
13 copy of that written document in the chart so that it  
14 is clearly documented.

15 CHAIRMAN CERQUEIRA: Cathy.

16 MS. HANEY: I would say, one -- and in  
17 John's comment about discussing it at the last  
18 meeting, we can go ahead with that recommendation.  
19 But what I need you to do is to give me some examples  
20 of an error, real life examples of an error. Maybe  
21 just 2 or 3.

22 DR. VETTER: An error in what?

23 MS. HANEY: Well, if we go back to the  
24 ACMUI's recommendation of the report -- let me pull it  
25 back up here for you. That was the ACMUI

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 recommendation. Let me have an example of an error in  
2 the release of the patient, and what I am looking for  
3 is a real example that I can put into a document.

4 CHAIRMAN CERQUEIRA: Okay. John, and then  
5 Nekita.

6 MR. GRAHAM: I will give you a simple  
7 example of the error in the delivery of the  
8 instructions, and that would be the lack of clear  
9 documentation that no one gave instructions to the  
10 patient.

11 CHAIRMAN CERQUEIRA: That is a pretty  
12 clear example. Ruth.

13 MS. MCBURNEY: If there is an error in the  
14 calculation of the dose, the estimated dose, and not  
15 following the guidance on how to do that.

16 MS. HANEY: That would be found like when  
17 you went back and did an audit of your own records,  
18 and something that you found at that point?

19 MS. MCBURNEY: Right.

20 CHAIRMAN CERQUEIRA: So those are I think  
21 two clear examples of issues, and are there any other  
22 examples? Lou.

23 MR. WAGNER: Ruth, I agree entirely with  
24 your comment, except for one aspect. Just because you  
25 don't follow guidance is not a criteria.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 MS. MCBURNEY: Right.

2 MR. WAGNER: I mean, guidance is not a  
3 rule. So you miscalculate somehow, but get the  
4 guidance issue out of it.

5 MS. MCBURNEY: It is totally that your  
6 estimate is off.

7 MR. WAGNER: That your estimate is totally  
8 off, right.

9 CHAIRMAN CERQUEIRA: Other examples or  
10 other comments for Cathy?

11 (No audible response.)

12 MS. HANEY: Okay. And I think the last  
13 two questions I think we have really covered, or I  
14 have enough information from what you have talked  
15 about already to fill in the answers to the other two.

16 CHAIRMAN CERQUEIRA: I guess I understand  
17 the Commission's concerns about the public, but I  
18 think certainly at our last discussion in November,  
19 and in all of the discussions here, we don't really  
20 feel that it is going to reassure patients that it  
21 really deals with an issue.

22 And again from your own estimate of the  
23 numbers, it has not been a problem. So by creating a  
24 specific policy, I think you are going to probably  
25 frighten the public more into thinking that this is an

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 ongoing problem, when in reality it has not been a  
2 problem. Jeff.

3 MR. WILLIAMSON: This whole issue, I  
4 guess, is prompted by -- or this rule making  
5 initiative is prompted by an SRM from the Commission.

6 MS. HANEY: Right.

7 MR. WILLIAMSON: Maybe this would be  
8 appropriate for us to speak to the Commission directly  
9 about this during our briefing, which I guess we  
10 didn't have this year.

11 CHAIRMAN CERQUEIRA: That's correct.

12 MR. WILLIAMSON: And which we have around  
13 this time though don't we?

14 CHAIRMAN CERQUEIRA: That's correct.

15 MS. HANEY: We have had them in the spring  
16 and the fall. It kind of varies on when there is a  
17 need to address the Commission with a topic.

18 MR. WILLIAMSON: But is there some way the  
19 staff could respond to the Commission with these  
20 concerns about their requirement and to ask them to  
21 consider modifying it?

22 MS. HANEY: The minutes or the summaries  
23 of these meetings and the transcripts are available to  
24 the Commissioners, and when we were doing the formal

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701



1 meetings before they were being read by the  
2 Commissioner's assistants.

3 So the Commission is made aware of the  
4 ACMUI's views of this, and since you still have the  
5 formal recommendation on the book, they obviously are  
6 aware of that. So I guess it is kind of open, Jeff.

7 The words do get to the Commission. When  
8 we forward the proposed rule that we are working on to  
9 the Commission, there is always a section in the  
10 Commission paper, as well as in the Federal Register,  
11 that talks about discussing it with the ACMUI and what  
12 the ACMUI's views were.

13 So that is a second mechanism for getting  
14 it up there.

15 MR. WILLIAMSON: Let me put the question  
16 another way. Other than responding to the Commission  
17 with the requested rule, can you respond to the  
18 Commission with a concern that their requirement isn't  
19 reasonable, and would they consider modifying it?

20 MS. HANEY: We can --

21 MR. WILLIAMSON: Is there a mechanism for  
22 doing that?

23 MS. HANEY: Other than the mechanism of  
24 them getting a copy of the minutes, I don't know of

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 one, but that is not to say that we can't try  
2 something.

3 CHAIRMAN CERQUEIRA: I have learned from  
4 John that sometimes making motions and taking a formal  
5 vote sort of highlights things a little bit more when  
6 it comes out in the minutes. So, John, do you have a  
7 good motion to make?

8 MR. GRAHAM: I would just move that the  
9 ACMUI reaffirm its recommendations from November of  
10 2000 that a risk-informed reporting limit of five rems  
11 should be limited to reporting of errors made in the  
12 release of the patient, and/or reporting of errors  
13 made in delivery of instructions to the patient.

14 DR. NAG: I would not support that because  
15 that has gone before and I think I would like to amend  
16 that by giving the reasons, and the reason would be as  
17 you summarized, Manuel, that all the reasons that you  
18 summarized, that you add all of those reasons into  
19 that, and then it will be more forceful, and it will  
20 also explain why the ACMUI made those recommendations.

21 Otherwise, it is just a piece of paper  
22 that says the same thing that was there in the last  
23 meeting.

24 CHAIRMAN CERQUEIRA: So I think the  
25 comments that I had was that it was intrusive to the

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 patient and to the institution, and inappropriate  
2 publicity to the institution and the patient, and  
3 anonymity was recommended.

4 It is inaccurate -- it is impossible or  
5 inaccurate at best to estimate a dose. It is very  
6 resource intensive and it is impossible to implement,  
7 unworkable, unenforceable --

8 MR. WAGNER: And no precedent.

9 CHAIRMAN CERQUEIRA: And no precedent.

10 MS. HOBSON: And it does not add to the  
11 safety.

12 DR. NAG: And that it does not add  
13 anything to the safety.

14 CHAIRMAN CERQUEIRA: So do we want to add  
15 that to the motion? John.

16 MR. GRAHAM: We are getting wordy, I  
17 think, and it all just because a "where as" there. So  
18 if all of that is in the front end of a where as,  
19 therefore, the ACMUI recommends, and then everything  
20 that I stated in the motion.

21 CHAIRMAN CERQUEIRA: Do I have a second to  
22 the amended motion?

23 DR. NAG: I second.

24 CHAIRMAN CERQUEIRA: Any further  
25 discussion?

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 (No audible response.)

2 CHAIRMAN CERQUEIRA: If not, we should  
3 take a vote. All in favor?

4 (A chorus of ayes.)

5 CHAIRMAN CERQUEIRA: Any opposed?

6 MS. HANEY: Dr. Cerqueira, I think for the  
7 record that you need to say all in favor, or the  
8 number, or no opposed.

9 CHAIRMAN CERQUEIRA: All in favor? And  
10 let's see a show of hands. So we have 10 that are in  
11 favor. Any opposed?

12 (No audible response.)

13 CHAIRMAN CERQUEIRA: No opposition, and  
14 anybody who is a voting member who abstains? None.  
15 Okay. How could we make it any clearer.

16 MS. HANEY: Thank you.

17 CHAIRMAN CERQUEIRA: John informed me that  
18 his section will not take that long, and so any  
19 questions for Cathy on any of the additional points,  
20 in terms of this Part 35 revision process?

21 So give me an idea of the time lines  
22 again, Cathy. I sort of like time lines.

23 MS. HANEY: Do you want optimistic, or  
24 what?

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 CHAIRMAN CERQUEIRA: The OMB will  
2 basically -- let's say that under the best case  
3 scenario that on May 12th, they give us an answer and  
4 it says no problems. Let's go ahead and do it.

5 MS. HANEY: All right. Then I would say  
6 by about -- let's see. Within two weeks, by the end  
7 of May, we will have the rule to the Federal Register.

8 CHAIRMAN CERQUEIRA: So, May 31st, Federal  
9 Register.

10 MS. HANEY: By May 31st, and our  
11 experience with the proposed rule is because of the  
12 size of the document, it will take probably a week to  
13 get it published, where most things are usually  
14 published within 3 days.

15 So you have got another week there. Then  
16 there will be a six month implementation period,  
17 meaning that -- well, let me rephrase it differently.  
18 The rule will not be effective for six months. For  
19 those of you that were familiar with Part 20, you are  
20 able to start complying with the New Part 20 earlier.

21 You can't do that with Part 35, and there  
22 are various reasons why it is not structured to do  
23 that. But if you have questions, I can go into it.  
24 But you cannot implement the new rule for six months.  
25 So now we are looking at probably January of 2001.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 CHAIRMAN CERQUEIRA: 2002.

2 MS. HANEY: So January of 2002 as the  
3 effective date of the rule.

4 CHAIRMAN CERQUEIRA: So the best case  
5 scenario, January 1st, 2002. Now, what if the OMB  
6 decides that on May 12th that not only do they need  
7 more time, but they feel that there is issues. What  
8 sort of potential issues could there be?

9 MS. HANEY: Well, they did get some very  
10 good comments from the different professional  
11 societies, and the questions could be coming back to  
12 NRC and asking for us to justify our position. You  
13 know, why did you calculate this, or why did you  
14 figure it would only take 2 or 3 hours, when someone  
15 else says it is going to take longer.

16 So there might be some give and take there  
17 on questions asking us to justify what we put into the  
18 package, and usually there is explaining to do,  
19 because realize that the people that are at OMB are  
20 not familiar with the reg, and what medical uses of  
21 isotopes are, and they are looking at it from strictly  
22 the record keeping and reporting requirements.

23 And in other rules that I have seen going  
24 back and explaining what does this mean really, and so  
25 it is almost like a little bit of education there.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1                   CHAIRMAN CERQUEIRA:     But you don't  
2 anticipate -- I mean, you have not been led to believe  
3 by any of the feedback that you have gotten that there  
4 are going to be issues; is that correct?

5                   MS. HANEY:   No, I think there will be  
6 issues. I mean, this is me personally speaking. I  
7 think that there will be some conversations that take  
8 place going back and forth, where we are hoping to  
9 explain the rule to them, and where the record-keeping  
10 requirements are.

11                   And, for example, in the OMB package, we  
12 had to justify why the record was needed. So it is in  
13 words, but sometimes that is best, and you have to  
14 talk about what do those words mean.

15                   CHAIRMAN CERQUEIRA:   Now, does the ACMUI  
16 have any role in this process? I mean, we are  
17 basically the people that are using these medical use  
18 of isotopes, and do we have any input into them?

19                   We have obviously expressed our concerns  
20 and support of the revisions. Is there anything that  
21 we can do to facilitate implementation?

22                   MS. HANEY:   I think from the standpoint  
23 that if they ask me a question, or us a question that  
24 we are not able to answer from the standpoint of  
25 impact, or what does this mean, and I call you on the

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 phone and say help, that you guys would return my  
2 call.

3 And that would be -- and which you have  
4 always done. So let me not think that or leave the  
5 message that you have not been -- you know, been  
6 unresponsive.

7 And, for example, there was a case that  
8 came up when I was reviewing the package before it  
9 went to OMB in the therapy area, and I called down Dr.  
10 Diamond, and there were some numbers in the package,  
11 and I said does this sound reasonable.

12 So I think that is the biggest help that  
13 you could be, and whether it is me sitting in the  
14 position making the call to you or a member of John's  
15 staff, or whatever, making the call. Those are the  
16 sorts of things that the ACMUI can help us on.

17 CHAIRMAN CERQUEIRA: So the best case,  
18 January 1st, 2002, and if you could predict worst  
19 case?

20 MS. HANEY: Oh, gosh, can I do the old no  
21 comment? I would like to think that within a month or  
22 two of that, because when we do get the questions from  
23 OMB, we are going to respond to them very quickly.

24 It is not something that is going to go  
25 into a black hole and we are going to drag our feet on

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701



1       responding, because we are very anxious to get the  
2       rule published also. So I think worst case is two  
3       months, and so March of 2002.

4               CHAIRMAN CERQUEIRA: Okay. All right.  
5       Jeffrey, a comment?

6               MR. WILLIAMSON: Suppose just  
7       hypothetically the concerns that OMB raises are very  
8       serious and a change to the rule text might be  
9       contemplated. If that happens, what would that do to  
10      the time course of the implementation of the  
11      regulations?

12              MS. HANEY: Well, I guess there are a  
13      couple of things, Jeff. Is there would be significant  
14      concerns, obviously we would or could go back and look  
15      at the rule, and go back to the Commission and say  
16      this came up during the OMB process and how should we  
17      handle it at this point, and should we stop the rule.

18              So I guess we could come to a total  
19      stopping on it. More than likely, maybe we would go  
20      into a situation where we would let this rule go by,  
21      but immediately start working on a revision to the  
22      rule to address the issue.

23              I mean, we already have one working, but  
24      to start a second revision to the rule. So ideally  
25      you want to put out the perfect rule, but it doesn't

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 work all the time, and that's why we have the process  
2 for revising the rules.

3 The third option is that NRC can override  
4 OMB's approval. We did do that -- or lack thereof  
5 actually. We did do that with the quality management  
6 rule before. So we would have the option of saying,  
7 okay, we just feel that this is necessary, and  
8 therefore we need to go forward.

9 MR. WILLIAMSON: But would making a change  
10 to the rule text at this point be going back to square  
11 one and starting the whole process all over? If you  
12 did change the text, how much extra time would it add  
13 minimum to the implementation date? That's my  
14 question.

15 MS. HANEY: That is probably something  
16 that I would need OGC counsel on, because we have got  
17 an affirmed rule at this point, which means that the  
18 Commission has approved it.

19 If we were to make anything more than real  
20 minor, or what we would call an administrative change  
21 to the rule text at this point, you would have to go  
22 back and go through the public comment period, and the  
23 finalization again, because then we are still under  
24 the Administrative Procedures Act.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1                   And I think, Marjorie, if you would care  
2                   to add anything to that, because now you have kind of  
3                   stepped beyond my expertise.

4                   MS. ROTHSCILD: Marjorie Rothschild from  
5                   the Office of General Counsel. All I would say is  
6                   that obviously it would be a case by case situation,  
7                   and the particular change would have to be looked at,  
8                   and the nature of it assessed to determine what the  
9                   appropriate procedure would be for dealing with that.

10                  MS. HANEY: Thank you very much, Cathy.  
11                  Now, what is your retirement date? I just want to  
12                  make certain that this gets done before that?

13                  MS. HANEY: Well, actually, as it stands  
14                  right now, I am in my current position for another  
15                  week-and-a-half, and then I move to another division  
16                  in the Office of Nuclear Materiel Safety and  
17                  Safeguards, and start a new job.

18                  I did alert my new supervisor to the fact  
19                  that I still needed to be available to support Part 35  
20                  through OMB. So, in essence, actually I am closer to  
21                  John's office with my new job than I am right now.

22                  So I am still going to stay available for  
23                  help in looking at some of the documents that go out,  
24                  and I will stay with the process through the OMB  
25                  approval.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 CHAIRMAN CERQUEIRA: Thank you very much,  
2 Cathy. John, 10 CFR Part 35 Transition and  
3 Implementation Issues.

4 MR. HICKEY: Thank you. I don't have a  
5 visual presentation for this segment, and I will be  
6 brief. Some of the transition issues are also items  
7 that are later on the agenda, and so I won't address  
8 those.

9 But as Cathy has already discussed, this  
10 is a time line here and in that context, we need to be  
11 thinking about what we are doing now, and what we are  
12 doing over, let's say, the next 11 or 12 months until  
13 the effective date of the rule.

14 And then what we will be doing after the  
15 effective date; and in the last meeting, Members of  
16 the Committee, we discussed with you implementation in  
17 general, and also outreach, and just to remind you  
18 that a lot of our efforts now are focusing on  
19 outreach, both internally to inform the NRC staff of  
20 what is in the new rule, and how life will be  
21 different under the new rule.

22 And also informing the medical community  
23 and the members of the public at large what is going  
24 to be in the new rule, and answer their questions.  
25 One of the things that we -- well, to go in order. We

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 are going to have our own training and workshops for  
2 our own staff, and for the agreement, because the  
3 agreement states regulate the majority of medical  
4 facilities as you know.

5 And we are going to accept as many  
6 invitations as we can to attend society and licensee  
7 meetings, and that process has already started, where  
8 we explain what is in the new rule, and how we see  
9 life as different under the new rule.

10 There is one other area that is a  
11 significant change and it is not an item on the  
12 agenda, and that is the New Part 35 will for the first  
13 time formally recognize what we call our sealed source  
14 and device registry, which is where the sealed  
15 sources, such as brachytherapy sources, or devices  
16 such as gamma stereotactic devices, are reviewed, and  
17 undergo a design and safety review, and they are,  
18 quote, registered in this registry.

19 So Part 35 will for the first time give  
20 recognition to that registry. So we need to look at  
21 -- and most of those registrations are issued by  
22 agreement States. So it is a cooperative effort  
23 before NRC and the agreement States.

24 We need to look at that registry process  
25 in light of the new rule, because some of the

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 registration sheets old, and don't even reflect some  
2 of the necessarily developments in the existing Part  
3 35, much less the new part 35.

4 And also they were not written with  
5 anticipation that Part 35 would give recognition to  
6 the registry. So that is an effort where we are going  
7 to be working among our own staff and the agreement  
8 States to perhaps revise or issue guidance on the  
9 existing registrations, and also guidance for the new  
10 registrations so that they anticipate the New Part 35.

11 So that was all that I had to say on this  
12 topic, but I would be happy to answer any questions.

13 CHAIRMAN CERQUEIRA: David.

14 DR. DIAMOND: John, would you please tell  
15 me what you think this formal recognition of the  
16 device registries is, and what that will produce, and  
17 what type of benefits it will produce? I am curious  
18 to see how this is going to -- I know it is going to  
19 be helpful, but tell me what you anticipate.

20 MR. HICKEY: Yes. It allows us in the  
21 community to have more flexibility in keeping up with  
22 new technologies. The way the current Part 35 is  
23 structured, it says that you can use radioactive  
24 material for teletherapy, or you can use it for

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 cancer, or you can use a nuclide, cesium 137, for a  
2 certain cancer treatment.

3 You can use strontium 90 for a certain  
4 type of treatment. So it didn't allow for new uses of  
5 the radioactive material, or I shouldn't say it didn't  
6 allow. It had limited flexibility when new uses, and  
7 new nuclides, and new forms came along, such as using  
8 -- we now have, for example, intravascular  
9 brachytherapy work in liquid gas and sealed sources in  
10 that area.

11 We have gamma stereotactic treatments,  
12 which are not flushed out in the old Part 35. We have  
13 high dose and other remote after loaders which are not  
14 flushed out in the Part 35. We feel by covering these  
15 in a more general and flexible manner in the New Part  
16 35 that it will make authorizations for these new  
17 technologies less cumbersome.

18 CHAIRMAN CERQUEIRA: Other questions for  
19 John? If not, I guess we can take a slightly longer  
20 break, and we will reconvene at 10:00.

21 (Whereupon, the meeting was recessed at  
22 9:35 a.m., and resumed at 10:00 a.m.)

23 CHAIRMAN CERQUEIRA: All right. I would  
24 like to reconvene the committee, and we will start  
25 with the first item on the agenda, which is the

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 Recognition of Certification Boards, which will be  
2 presented by Bob Ayres from the NRC.

3 And then we are going to have a five  
4 minute presentation, I believe, by Dr. Michael Gillin,  
5 from the Medical College of Wisconsin, and we will  
6 hold all of the questions until both Bob and Dr.  
7 Gillin have made their presentations. Bob.

8 MR. AYRES: Okay. I will start by saying  
9 that with regard to questions, if anybody has a  
10 question regarding clarification of something that I  
11 am talking about, why we can address that as we go  
12 through it.

13 CHAIRMAN CERQUEIRA: Okay.

14 MR. AYRES: But the other questions after  
15 Dr. Gillin's talk, we can then address all the issues.  
16 Okay. I am talking for a second time here about our  
17 board recognition process, which has changed with the  
18 New Part 35, and that we are going to be listing these  
19 on a website instead of contained in the regulations  
20 for the same reasons that John Hickey talked about for  
21 the SNDs, as it gives us more flexibility to make  
22 changes without having to do rule making.

23 These were the boards that we discussed  
24 with you at the last committee meeting, just to remind  
25 you of what we did cover. Certainly I am willing to

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701



1 entertain any questions at the end of both of our  
2 presentations on any of the previous issues that we  
3 did talk about.

4 And what we have had since the last ACMUI  
5 meeting is that we have had four boards submit new  
6 material to us. In some cases, they were on the  
7 previous list, but they submitted updated or new  
8 material, such as the American Board of Nuclear  
9 Medicine, and the American Board of Radiology came in  
10 with their positions.

11 We have had a new submission from the  
12 American Board of Science and Nuclear Medicine, and  
13 the Certification Board of Nuclear Cardiology. Going  
14 through these new submissions in-turn, the American  
15 Board of Nuclear Medicine sent us a letter in  
16 November, and the intent of this was that they also  
17 wished to be recognized, in addition to their 35.100  
18 and 35.200, and so forth, authorizations.

19 And to be recognized as meeting the  
20 requirements to serve or to be recognized as an  
21 authorized or named as an RSO, radiation safety  
22 officer.

23 The American Board of Radiology submitted  
24 their formal letter to us and listing those modalities  
25 which they were seeking recognition, and those were in

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 diagnostic radiology in 35.190, 290, and 390, except  
2 for one of the special modalities listed under (g)(2)  
3 under 390.

4 And in radiation oncology, 35.392, 394;  
5 radiopharmaceutical therapies, 35.490, the manual  
6 brachytherapy; and 35.491, which is the I-applicator;  
7 and 35.690, which includes teletherapy, gamma  
8 stereotactic radiosurgery, and remote after loader.

9 And in radiological physics, they asked  
10 for the radiological physicist to be recognized both  
11 as RSOs and as Medical Physicists under 35.50, and  
12 35.51, respectively.

13 And they also again raised a couple of  
14 questions that had previously been issued. This time  
15 we worked or we sent a formal reply to a letter from  
16 Dr. Hendy, which has been reviewed by our Office of  
17 General Counsel, and so we more or less have at least  
18 an interim final position on these.

19 And one of the real issues here was the  
20 500 hours of separate work experience for each of  
21 these therapeutic modalities differs either in their  
22 entirety or nearly so, and the question was for this  
23 board's diplomates to be certified under all of these  
24 different therapeutic modalities, would they need to

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1       sum all of those 500 hours from each of these  
2       modalities.

3               And our response was no, but the work  
4       experience items, which differ, and most of them do,  
5       in each of the tasks listed under b(1)(ii) for each of  
6       these modalities would have to -- they would have to  
7       have shown evidence of having work experience in each  
8       of those.

9               Now, that may be more than 500 hours, and  
10       it may not be. We are saying that it is a minimum of  
11       500 hours for all of these modalities, and whatever  
12       additional hours is necessary to accomplish the  
13       experience without putting any number to those.

14              In other words, somebody who is obviously  
15       qualified in 35.400, which is the manual  
16       brachytherapy, and the work experience requirements  
17       for radiopharmaceutical therapy, are quite different,  
18       and I am sure that all of you recognize that.

19              The other issues was can the clinical  
20       training, which is typically three years of a medical  
21       physicist, be recognized under 35.50, the radiation  
22       safety officer training and experience requirements,  
23       for authorization as a radiation safety officer.

24              The answer is, yes, provided -- and there  
25       is really a question here of whether the board

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 requirements meet this, but they have in that three  
2 year training at least one year of this training is  
3 under the supervision of an RSO, and that that RSO  
4 signs the appropriate preceptor statement certifying  
5 that one year of supervised radiation safety officer  
6 training has been received.

7 What is recognized, and it is relevant  
8 because a number of the boards have come in asking for  
9 authorization under 35.50 for their people, for their  
10 diplomates to be authorized as radiation safety  
11 officers.

12 And they don't really -- and they all come  
13 in under 35.50(b), which is a more rigorous training  
14 and experience requirements that really were intended  
15 for appointing dedicated and trained RSOs for large  
16 programs, with mobile medical disciplines being  
17 practiced.

18 And 35.50(c) says that an authorized  
19 medical physicist, authorized medical user, or  
20 authorized nuclear pharmacist, purely on the basis of  
21 those authorizations and listing on the license, and  
22 has experience in the radiation safety aspects of  
23 using similar types of materials, can be appointed an  
24 RSO for those programs.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1           So it is relatively straightforward to  
2     appoint a diagnostic imaging nuclear medicine  
3     authorized user to be the RSO for an imaging program,  
4     or a medical physicist to be an RSO for a therapy  
5     program, or an authorized nuclear pharmacist to be the  
6     SRO for a pharmacy.

7           And when you get into the more complex  
8     appointment requirements in (b) when you have multiple  
9     programs, such as imaging mobile therapies and  
10    pharmacy all rolled into one, and then you are looking  
11    at the more experienced RSO qualifications under (b).  
12    Yes, Jeff.

13           MR. WILLIAMSON: Wouldn't the appointment  
14    of a radiation safety officer always require a  
15    licensed amendment?

16           MR. AYRES: Yes. I am simply addressing  
17    it from the perspective of board recognitions at this  
18    point. But if there is no board recognition, any  
19    individual can come in and present the appropriate  
20    training and experience requirements, and if they  
21    satisfy those, be appointed to whatever authorization  
22    they request.

23           This is applicable to all of the  
24    authorized users and medical physicists, and nuclear  
25    pharmacists on the license. They have to be listed on

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 the license obviously if they are applying for that  
2 additional authorization.

3 Where it comes in to be a problem, and as  
4 I go through these, it would not appear to be  
5 applicable to those board certifications that don't  
6 result in authorized user status.

7 And there are two of them in the current  
8 submissions that we have. There is the American Board  
9 of Radiology certification of a medical nuclear  
10 physicist, because we don't have authorized medical  
11 nuclear physicists, and so there is no authorized  
12 status there.

13 Nor the American Board of Specialties in  
14 Nuclear Medicine Board Certification, and Nuclear  
15 Medical Science, which is kind of a specialized  
16 certification, and which has only been recognized in  
17 the present Part 35 for RSO certification.

18 CHAIRMAN CERQUEIRA: Richard, perhaps you  
19 could comment. You know, as sort of the RSO  
20 representative on the Board, is this acceptable you  
21 think from --

22 DR. VETTER: Well, as Mr. Ayres outlined,  
23 or at least as the way I heard it, an authorized  
24 medical physicist could be appointed an RSO for a

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 therapy program, but not necessarily for a broad scope  
2 program.

3 MR. AYRES: What we would simply ask is if  
4 they had experience with the other materials and they  
5 could demonstrate that, and we could make the  
6 appointment broader.

7 DR. VETTER: Right, and that seems  
8 reasonable to me.

9 CHAIRMAN CERQUEIRA: But this is something  
10 that could be done by the local committee if it  
11 exists?

12 MR. AYRES: No. Under both Part 35s, the  
13 RSO is deemed sufficiently important to radiation  
14 safety that they must be listed by name on the  
15 license. So it always requires an amendment to  
16 appoint an RSO under any circumstance.

17 CHAIRMAN CERQUEIRA: And, Ruth, in terms  
18 of the agreement States, do you see a problem with  
19 this?

20 MS. MCBURNEY: No. What I didn't  
21 understand is that it has authorized medical  
22 physicist, but that's not applicable to the board  
23 certification?

24 MR. AYRES: Well, the only time a licensee  
25 would apply for an authorized medical physicist, the

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1       only requirement for having one, and therefore, they  
2       get the deemed status if you would, is for therapeutic  
3       perimeters.

4                   MS. MCBURNEY:   Right.

5                   MR. AYRES:   We have no requirements for a  
6       medical physicist for a nuclear medicine program.

7                   MS. MCBURNEY:   That's true.

8                   MR. AYRES:   So there is no such thing in  
9       our regulations as an authorized nuclear medicine  
10      physicist.

11                  MS. MCBURNEY:   I see.   So it is in the  
12      nuclear physics rather than therapeutic?

13                  MR. AYRES:   Yes.

14                  DR. VETTER:   So as I understand it, if a  
15      licensee wanted to appoint their authorized medical  
16      physicist as their RSO, but the medical physicist had  
17      no experience in nuclear medicine, then it would not  
18      be likely that the NRC would approve this person to be  
19      the RSO for the entire institution?

20                  MR. AYRES:   Or we might require them to  
21      acquire the necessary experience, or to apply, or  
22      something.   We are getting so far ahead now where we  
23      are at that I can only speculate.

24                  CHAIRMAN CERQUEIRA:   Lou.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701



1                   MR. WAGNER: Could you explain this last  
2                   item here for me a little bit. Does this mean that a  
3                   board certified nuclear medicine physicist, or a board  
4                   certified nuclear medicine science person, board  
5                   certified in nuclear medicine science, could not serve  
6                   as an RSO on a license that just uses diagnostic  
7                   materials?

8                   MR. AYRES: Not under 35.50(c), because  
9                   they would not be listed on the license as a medical  
10                  physicist. Now, if they met the requirements of  
11                  35.50(b), yes. Again, let me get to this particular  
12                  board. It is coming up.

13                  MR. WAGNER: That would be good.

14                  CHAIRMAN CERQUEIRA: Okay. Jeffrey, you  
15                  have a question?

16                  MR. WILLIAMSON: Well, I will ask if it is  
17                  appropriate first. I have a question about the  
18                  radiation oncology certification, but since we are in  
19                  the middle of RSO, I don't know if you want to  
20                  entertain it at this time.

21                  CHAIRMAN CERQUEIRA: Let's bring it on at  
22                  a later time.

23                  MR. AYRES: Right after our last meeting  
24                  with the committee here, we got the letter from the  
25                  Board of Nuclear Cardiology, and I have looked it

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 over, and I see no problems, and it appears to meet  
2 all of our requirements for recognition of the board  
3 diplomates under 35.290.

4 And again these people, just as in the  
5 footnote, would appear to be able to serve as RSOs for  
6 an imaging program under the requirements of 35.50(c).

7 DR. ALAZRAKI: Can I make a comment on  
8 that?

9 MR. AYRES: Yes.

10 DR. ALAZRAKI: The nuclear cardiology  
11 individuals are trained in nuclear cardiology and not  
12 in general diagnostic nuclear medicine, or any  
13 therapeutic aspect of the practice. I don't think  
14 that those individuals would be appropriate as RSOs.

15 MR. AYRES: If you look at the New Part  
16 35, we make no distinction. If they meet the training  
17 and experience requirements for 35.290, they have got  
18 full authority, the same authority as anybody else,  
19 for both imaging and serving as an RSO.

20 DR. ALAZRAKI: I think that is dangerous.

21 MR. AYRES: Well, that is what the rule  
22 says. Yes?

23 DR. ALAZRAKI: Bob, would that person  
24 under this 35.290 also be able to serve as an RSO for  
25 therapy as well?

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 MR. AYRES: No.

2 DR. NAG: Or only for nuclear cardiology?

3 MR. AYRES: Under 35.50(c), it is for  
4 those materials for which you have the experience. I  
5 would expect that most of these individuals wouldn't  
6 have experience in therapy, and therefore we would not  
7 authorize it.

8 DR. ALAZRAKI: They also would not have  
9 experience in labeled white cells and handling of --

10 MR. AYRES: Well, that is not an issue  
11 here.

12 DR. ALAZRAKI: Well, it is a radiation  
13 safety issue.

14 MR. AYRES: Well, the training and  
15 experience requirements for 35.290 is the same for  
16 whether the background is nuclear cardiology or  
17 diagnostic nuclear medicine. That is the way the rule  
18 reads.

19 I am not going to address whether it is  
20 good, bad, or indifferent. I was not a part of  
21 writing that rule.

22 CHAIRMAN CERQUEIRA: Richard.

23 DR. VETTER: Just to comment briefly on  
24 that. If a physician is qualified under 290, then

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1       they would become -- they could be approved as the  
2       RSO.

3                   MR. AYRES:   That's right.

4                   DR.    VETTER:       But    many    nuclear  
5       cardiologists actually don't qualify under 290.  They  
6       practice in conjunction with a nuclear medicine  
7       physician as a team, and therefore they would not be  
8       qualified to do this.  On if they were fully qualified  
9       under 290.

10                  MR. AYRES:  And that is what 35.50 says.  
11       They have got to be listed on the license as  
12       authorized under 35.290 in order for them to be  
13       considered for RSO status.

14                  DR. VETTER:  Right.

15                  MR. AYRES:  Okay.  We are getting outside  
16       of the issue here a little bit, but let me go on.  The  
17       American Board of Science and Nuclear Medicine, they  
18       have simply only a single request, and they request  
19       recognition of their diplomates for 35.50, the RSO.

20                  They appear to lack -- and this is a  
21       preliminary position, as we may go back and ask some  
22       more questions, but they appear to lack the required  
23       one year full-time radiation experience serving as an  
24       RSO or training as an RSO, and the requisite RSO  
25       preceptor statement.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1           And they don't have the pathway under  
2   35.50(c) because they would not be listed on the  
3   license as an authorized user because this is the only  
4   certification that this board has. It has three  
5   variations on that.

6           CHAIRMAN CERQUEIRA: Bob, I am not  
7   familiar with this board.

8           MS. MCBURNEY: I'm not either.

9           CHAIRMAN CERQUEIRA: Naomi.

10          DR. ALAZRAKI: They are similar to the  
11   nuclear cardiology certification type of board. This  
12   is the same sort of thing. It operates through the  
13   Society of Nuclear Medicine, and they have their  
14   certifying exams just the way the nuclear cardiology  
15   board does.

16          You see, you have to distinguish boards.  
17   We use the use board very loosely here. There are  
18   boards which are approved by the American Board of  
19   Medical Specialties Society group, and there are other  
20   boards which are just certifying exam boards.

21          MR. AYRES: I am simply listing the board  
22   titles as submitted to us here.

23          CHAIRMAN CERQUEIRA: Now, is this for  
24   physicians or --

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 DR. ALAZRAKI: No, it is for scientists,  
2 physics and chemistry.

3 DR. SCHWARTZ: It is mainly physics and  
4 chemistry.

5 MR. AYRES: It in some degree is a little  
6 bit analogous to the ABR certification of nuclear  
7 medicine physicists, only this is not -- this is even  
8 more general.

9 DR. ALAZRAKI: Yes.

10 MR. AYRES: A more general science  
11 background in nuclear medicine is what this board  
12 considers.

13 DR. SCHWARTZ: And there aren't a large  
14 number of physicists there that are licensed under  
15 this board.

16 MR. AYRES: I am sure that many of you  
17 here at the table are more expert or have more  
18 expertise in exactly what these boards' backgrounds  
19 are and history.

20 CHAIRMAN CERQUEIRA: And the last  
21 implications that these would not qualify to be RSOs,  
22 is that --

23 MR. AYRES: It doesn't appear to be from  
24 their submissions and we will certainly get back to  
25 that, but all of the ones citing nuclear medicine, and

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 the medical physicists boards, and this board, and  
2 others, and even the American Board of Health Physics,  
3 have problems and/or questions about meeting the  
4 specific one year of dedicated experience under the  
5 supervision of an RSO in a medical program, and the  
6 corresponding preceptor statement.

7 And I did want to emphasize that the  
8 alternate pathway for many of these, which already  
9 authorized user status, can be readily appointed as  
10 RSOs for a program in which they have experience with  
11 the materials.

12 I simply -- and a quick little summary  
13 here of the different boards and all of the different  
14 specializations in which they applied, and you can see  
15 the Board of Health Physics, and the Board of Nuclear  
16 Medicine, the Board of Pharmaceutical Specialties, the  
17 American Board of Medical Physics, the Board of  
18 Radiology, and the American Board of Science and  
19 Nuclear Medicine -- well, anyway, there are eight  
20 boards that applied for RSO status under -- all of  
21 them under 35.50(b), which is the wide experience area  
22 of RSO, and probably all of them have difficulties, or  
23 at least on the surface going in have difficulties  
24 with the one year and the preceptor statement.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1           The bottom entry you can forget about. I  
2           intended to delete that and I didn't. Another group  
3           applied for recognition, and there is a 200 hour  
4           training requirement which would only be a subset of  
5           any certification process.

6           What are the options for board  
7           recognition? Well, clearly the most favorable one is  
8           that they all meet all the stated requirements of the  
9           rule, and are recognized and listed on our website as  
10          doing so.

11          The one issue that I need to raise with  
12          our Office of General Counsel is when a board  
13          partially meets the requirements, and I will give an  
14          example, because I know it is an issue here, and I  
15          think that Dr. Gillin might be talking about it, would  
16          be that the American Board of Medical Physicists,  
17          there may be issues because there are a very limited  
18          number of stereotactic radiosurgery units of obtaining  
19          work experience as a part of their training and board  
20          certification with the gamma knife, and could we in  
21          that situation give partial recognition.

22          In other words, the American Board of  
23          Medical Physics is deemed recognized for 35.400 to  
24          35.600, except for stereotactic radiosurgery, and then  
25          they could just come in with additional training and

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701



1 experience if they got into gamma knife later in that  
2 facility, or moved somewhere else and shown that they  
3 filled in the remaining T&E requirements for that  
4 modality.

5 That is a question that the rule does not  
6 say anything about partial certifications. So we need  
7 to get an opinion on that. I don't know the answer  
8 yet. And, of course, the last one is that they don't  
9 meet the rule requirements, and then there is no  
10 recognition.

11 And the options always exists for the  
12 licensees to submit proof that the individuals meet  
13 the requirements for training and experience for  
14 review by NRC, and as you know, if we have questions,  
15 we often come to this committee for your input on  
16 those kinds of reviews.

17 And they can be recognized as authorized  
18 users for the appropriate modality for which they meet  
19 the training and experience requirements.

20 Instead of a discussion now, what I would  
21 like to do is ask Dr. Gillen to come up and to have --

22 CHAIRMAN CERQUEIRA: Bob, before Dr.  
23 Gillen, let me just try to get a little clarification,  
24 because we are initiating a procedure which is going  
25 to be operative once the Part 35 revision rule is

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 approved, and so far we have had several discussions  
2 about boards. Now, have any of these boards that have  
3 submitted been notified of the actions of the NRC?

4 MR. AYRES: No, and for a couple of  
5 reasons. Well, I stand corrected on that. We just  
6 recently sent a letter to Dr. Hendy, who is the  
7 American Board of Radiology, and I believe he is the  
8 executive director, and with the response that I just  
9 gave you today about the summation of hours, and the  
10 medical physics issues.

11 That had been reviewed by our Office of  
12 General Counsel, and so we have at least an official  
13 position at this point, but we are kind of holding on  
14 this until we are sure the rule is a rule.

15 I do know that the medical physics  
16 representative has sent a letter to OMB on the medical  
17 physics issues, and so we have no assurance that what  
18 is currently with OMB will be the final rule, although  
19 I am hopeful that that will be resolved soon and we  
20 can go ahead.

21 CHAIRMAN CERQUEIRA: Right. It would be  
22 important to have a plan, in terms of is there going  
23 to be a best case scenario. January 1st, 2002, the  
24 rule will go into effect, and at that point we should  
25 officially -- well, I guess we can't notify people

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1       until -- I guess one it has been published in the  
2       Federal Register, then people could be notified.

3               MR. AYRES:   Yes.

4               CHAIRMAN CERQUEIRA: And so we are talking  
5       maybe June would be the official date. And it gets  
6       fairly complicated, because we are talking about  
7       authorized physicians users, and we are talking about  
8       RSOs, and we are talking about medical physicists.

9               MR.   AYRES:       And   multiple   medical  
10       modalities   for   authorization,   particularly   of  
11       authorized users. I am working on it, and I plan to  
12       hopefully at least have OGC, our Office of General  
13       Counsel, review a lot of these issues before certainly  
14       your next meeting, and actually establishing a website  
15       right around the time the rule becomes final.

16               And that would list certifications, and we  
17       have not made various decisions on such things as  
18       maybe we would do some question and answer postings on  
19       that website, too. That's a possibility.

20               And the other thing is management has not  
21       made some decisions. We think we may go back to some  
22       of the boards and ask some specific questions where we  
23       have some concerns, particular about preceptor  
24       statements, and where it is not clear that they do or  
25       do not require them.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1                   CHAIRMAN CERQUEIRA: I think it would be  
2 helpful to the committee to have some idea of where  
3 the process stands relative to these various boards  
4 that have applied, and for what they are applying,  
5 because it was a little hard for me to follow it just  
6 sort of seeing it for the first time up there.

7                   MR. AYRES: It is in staff review right  
8 now.

9                   CHAIRMAN CERQUEIRA: Yes. Now, would it  
10 be possible to get things out to the committee members  
11 and just sort of keeping them notified of the status?

12                  MR. AYRES: I thought that is what I was  
13 doing here. We will try and keep you in the loop. We  
14 have not yet reached any formal responses to any of  
15 these issues other than the ABR, two questions that  
16 were recently addressed in a letter back to Dr. Hendy.

17                  CHAIRMAN CERQUEIRA: Right.

18                  MR. HICKEY: Mr. Chairman, this is John  
19 Hickey.

20                  CHAIRMAN CERQUEIRA: Yes.

21                  MR. HICKEY: I would like to suggest -- I  
22 think that your points are well taken. What our plan  
23 was to -- assuming that the rule -- applying the rule  
24 as it is at OMB now is to respond to the boards, and  
25 tell them which ones meet the requirements, and answer

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 the questions of the boards that have questions so  
2 that they are on notice.

3 And then if the rule doesn't change, the  
4 boards that appear to meet the requirements and  
5 recognition, we would formally issue the recognition.  
6 So what I would like to do is clear the issues that  
7 are on the table within 30 days.

8 And we could also provide the members of  
9 the committee with a summary in that same context of  
10 where things stand.

11 CHAIRMAN CERQUEIRA: I think that would be  
12 useful, and I think it should probably be a uniform  
13 notification date for these boards, because to try to  
14 respond to one and not the others, and just sort of  
15 standard operating procedures about something that is  
16 submitted, there should be a reasonable time of  
17 response, and it should be sort of uniform and  
18 consistent. So I think that would be useful.

19 MS. ROTHSCHILD: Mr. Chairman, Marjorie  
20 Rothschild from the OGC, the Office of the General  
21 Counsel.

22 CHAIRMAN CERQUEIRA: Yes, Marjorie.

23 MS. ROTHSCHILD: I just wanted to clarify  
24 two things. The rule is at OMB for review of the  
25 paperwork aspects of it, record-keeping and reporting.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 So we would not expect that provisions that don't  
2 relate to that would change as a result of any OMB  
3 action, because the review is narrower than what we  
4 are talking about here.

5 And then the only other thing that I  
6 wanted to clarify is that there might have been an  
7 implication that the rule is effective upon  
8 publication. I don't know if anybody directly said  
9 that, but as we recognize, there is an effective date.  
10 You know, a time period after which it would be  
11 effective.

12 CHAIRMAN CERQUEIRA: Cathy made the point  
13 that once it gets published that there is a 6 month  
14 period before it becomes implemented. So I was  
15 anticipating probably a June 1st publication and a  
16 January 1st direct implementation.

17 MS. ROTHSCHILD: Yes. I am not meaning to  
18 imply that actions can't be taken in terms of  
19 implementing the rule in anticipation of it becoming  
20 effective. Thank you.

21 MR. AYRES: If I gave you the impression  
22 that it was effective, my main point was that on  
23 publication it is final. So we know that we have a  
24 fixed target to work with. Also, that the -- well, I

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 had another thought, but I forgot it. So I will keep  
2 quiet and let you all talk.

3 CHAIRMAN CERQUEIRA: I guess the point  
4 that I was making was that it would be important since  
5 these boards are applying that we should have some  
6 sort of a uniform process in place for review, for  
7 notification, and for dealing with feedback.

8 MR. AYRES: This is all part of the  
9 implementation process that John Hickey talked about  
10 earlier, and that we are actually working on.

11 CHAIRMAN CERQUEIRA: One comment from  
12 Jeff.

13 MR. WILLIAMSON: Well, it is just a  
14 question for Bob. I didn't understand what the  
15 implications were of what you said regarding ABR  
16 certification in radiation oncology, or actually  
17 therapeutic radiology.

18 Did I understand you to say that you felt  
19 unofficially at this time that ABR certification in  
20 therapeutic radiology satisfied the requirements for  
21 300, 400, and 600?

22 MR. AYRES: Those look like it may for  
23 600. The problem or the rule says -- and again this  
24 be from our official position, in which our Office of  
25 General Counsel would play a big role.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 But what it says in these experience  
2 requirements is that it clearly says all, and in that  
3 all are the two stereotactic radiosurgery work  
4 experience requirements, which I understand can be  
5 problematical.

6 MR. WILLIAMSON: And what about  
7 radiopharmaceutical therapy, or therapeutic  
8 radiologists?

9 MR. AYRES: I don't understand what you  
10 are asking.

11 MR. WILLIAMSON: Do you feel now that ABR  
12 certification in therapeutic radiology meets the  
13 requirements, I guess in 35.390?

14 MR. AYRES: If they say they do. What we  
15 are asking is for the boards to self-certify, and if  
16 we have any questions, then we will follow up with  
17 questions.

18 MR. WILLIAMSON: And did they self-  
19 certify?

20 MR. AYRES: Not on the 600 issue. They  
21 raised questions about having met the training and  
22 experience requirements, and in particular for  
23 stereotactic radiosurgery. I would have to look. I  
24 had it on the chart for what they asked for, but --  
25 no, I've got the wrong one.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701



1                   MR. WILLIAMSON: Well, I guess I would  
2                   like to add my request to what our chairman said, that  
3                   for our community that a very short of detailed  
4                   breakdown of what exactly the status of the staff's  
5                   thinking at this time for the boards that are relevant  
6                   to our community be made.

7                   CHAIRMAN CERQUEIRA: I think that would be  
8                   helpful.

9                   MR. WILLIAMSON: This is just too sketchy.

10                  CHAIRMAN CERQUEIRA: Yes. This sort of  
11                  table -- and I don't even know what all the boards are  
12                  that are listed up there, and I think we have to be --  
13                  you know, I would like some more detail on this  
14                  provided in a way that we could give you some input.

15                  MR. WAGNER: Is that what was being  
16                  applied for or approved?

17                  MR. AYRES: This is what they applied for.  
18                  Nobody has been approved yet at this point, except  
19                  that everybody is approved under the current Part 35,  
20                  whichever way you want to look at it.

21                  The two that aren't listed there that are  
22                  on the existing rule, because we have not established  
23                  contact with them, are the two British boards by the  
24                  way, just as a comment. But I think maybe we should

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 have Dr. Gillin come up and give his presentation, and  
2 then have time for additional questions.

3 CHAIRMAN CERQUEIRA: A brief comment by  
4 Dr. Nag, and then we will move on.

5 DR. NAG: One question for you. For the  
6 therapeutic radiology, you are talking about gamma  
7 knife and the cobalt. The radiation, is there a  
8 difference between being approved for the use of it,  
9 in terms of the medical use, and where you do need  
10 extra training for the medical use of the gamma knife.

11 But in terms of the radiation safety  
12 issue, which is what the NRC is responsible for, those  
13 radiation safety issues are similar. So do you really  
14 need to know all about treatment planning on the  
15 gamma knife, which is quite different, to be able to  
16 be a radiation safety officer?

17 MR. AYRES: I would think so, because  
18 certainly adequate radiation treatment planning is a  
19 radiation safety issue.

20 CHAIRMAN CERQUEIRA: All right. If we  
21 could have Dr. Gillin. But again I think the intent  
22 of the board was to look at the risks that are  
23 involved and try to minimize the intrusiveness, but at  
24 the same time I don't want a nuclear cardiologist to

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 be an authorized user for a facility that is using I-  
2 131, where they have not had any experience.

3 And so I think the board could help to  
4 identify -- the ACMUI could help to identify some of  
5 these issues, but it isn't really clear to me what  
6 these boards are applying for, and whether they are  
7 physicists or physicians.

8 So I think that we need to avoid problems  
9 of implementation. We should be updated on some of  
10 these informations.

11 MR. AYRES: On the American Board of  
12 Physics, they clearly are applying an answer to Dr.  
13 Williamson's question of 35.400 and 600  
14 authorizations. I don't see anything on the  
15 radiopharmaceutical therapy that the board has  
16 submitted. I will be glad to go over it with you  
17 after during a break.

18 CHAIRMAN CERQUEIRA: All right. Dr.  
19 Gillen.

20 DR. GILLIN: Thank you, Mr. Chairman. As  
21 you know, the American Association of Physicists in  
22 Medicine is a 4,000 plus member organization, and  
23 mostly in the United States. The majority of AAPM  
24 members practice radiation oncology physics.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 I am Chairman of the Professional Council  
2 of the American Association of Physicists in Medicine,  
3 and I am here today representing them, although the  
4 record should indicate that I am also a board member  
5 of the American Board of Medical Physics.

6 I have three basic messages that I wish to  
7 bring to this committee. We are very grateful for the  
8 opportunity to address the ACMUI, and we do have  
9 concerns.

10 The first message that I have is that the  
11 AAPM is supportive of the new rule process for a  
12 variety of reasons, one of which is that the new rule  
13 process introduces the concept of an authorized  
14 medical physicist, which emphasizes the importance of  
15 a medical physicist's role in the safe and effective  
16 delivery of radiation therapy with by-product  
17 materials.

18 We do have explicit concerns, which is my  
19 second message, relative to paragraph 35.51, and  
20 paragraph 35.71. And to provide you with some  
21 background information, the modalities that we are  
22 discussing are teletherapy units, and the training  
23 experience requirements are addressed in the current  
24 Part 35.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1                   And gamma knife units, which have not been  
2 previously addressed, and high dose remote after  
3 loader units which have not been previously addressed.

4                   Some observations as a medical physicist.  
5 There is substantial overlap between the three by-  
6 product materials. Modality is relative to radiation  
7 safety, calibration, and quality assurance activities.

8                   Thus, teletherapy training and experience  
9 of medical physicists is well positioned to deal with  
10 either HDR or gamma knife therapies. The basic or the  
11 emergency concepts are similar. Radiation decay is  
12 radiation decay. Measurement techniques, which  
13 involve ionization chambers and radiographic film, are  
14 similar.

15                   CHAIRMAN CERQUEIRA: Dr. Gillin, John  
16 Graham wants to make a brief comment.

17                   MR. GRAHAM: Just a brief question. Do we  
18 have this? Do we have a written document so we can  
19 make notes on this statement? That is a question to  
20 the staff. I am saying specifically verbatim that  
21 observation. I have got the letter and I have read  
22 it, but --

23                   DR. GILLIN: A copy has been given to Mr.  
24 Hickey.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1                   MR. HICKEY:     Mr. Chairman, we just  
2     received this right before the session, but we can  
3     have copies and have it distributed to the committee.  
4     The only document that has been distributed to the  
5     committee is the actual previous written statement  
6     from AAPM.

7                   CHAIRMAN CERQUEIRA: I think that would be  
8     appropriate to get that.

9                   MR. GRAHAM: Now, are these observations  
10    the collective vote of the organization that you are  
11    representing? I just want to understand the basis of  
12    this verbatim statement.

13                  DR. GILLIN: I think I introduce this by  
14    saying that it was my observations as an experienced  
15    medical physicist.

16                  MR. GRAHAM: Okay.

17                  CHAIRMAN CERQUEIRA: I'm sorry, if you  
18    could please continue.

19                  DR. GILLIN: Thank you. My second  
20    observation is that there is a substantial overlap  
21    between by-product materials and non-by-product  
22    material modalities relative to radiation safety  
23    calibration and quality assurance activities.

24                  It is my opinion that the accelerators are  
25    significantly more complex in cobalt-60 teletherapy

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 units. Thus, a qualified medical physicist is well  
2 positioned to come in as an authorized medical  
3 physicist for teletherapy.

4 The external calibration protocols, which  
5 are published by the AAPM, include both accelerators  
6 and cobalt-60 units in the same protocol, with one  
7 notable addition relative to cobalt-60 units.  
8 Radiation concerns are similar for treatments.

9 The calculation of treatment times follows  
10 the same approach for teletherapy units and  
11 accelerators, et cetera. So, our concerns. We have  
12 philosophical concerns. One unintended consequence of  
13 the new criteria to become an authorized medical  
14 physicist might be to reduce the importance of board  
15 certification within the medical physics community.

16 The board certification process does not  
17 require experience with specific by-product material  
18 technologies. The focus of the board examination  
19 process is determined for a particular candidate to  
20 have sufficient knowledge and judgment to practice  
21 medical physics independently.

22 There are limited opportunities for  
23 medical physicists to obtain training prior to taking  
24 board examinations with cobalt therapy, teletherapy  
25 units, or with gamma knife.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1           The American Association of Physicists in  
2           Medicine, the American College of Medical Physics, and  
3           the American College of Radiology, have similar  
4           definitions for a qualified medical physicist.

5           All the definitions include board  
6           certification and continued medical physics education  
7           as a central element of their definition of a  
8           qualified medical physicist. One argument for young  
9           medical physicists to go through the expense and  
10          effort of taking the board certification examination  
11          was an easier path to be named on the NRC license  
12          using the old Part 35.

13          It is the AAPM's understanding of the New  
14          Part 35 that board certification essentially makes no  
15          difference. The New Part 35 requires the authorized  
16          medical physicist to be either board certified, whose  
17          certification process includes all of the training and  
18          experience requirements of paragraph (b), which the  
19          boards will be very reluctant to agree to, or have the  
20          same experience and not be certified.

21          If the current understanding of the AAPM  
22          is correct, it is the opinion of the AAPM that the New  
23          Part 35 poses a long term negative public health issue  
24          by having the qualifications of a medical physicist

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433



1 being defined one way by professional organizations,  
2 and another way by regulatory agencies.

3 Even if the AAPM's understanding is not  
4 correct, it is important for the ACMUI to understand  
5 that AAPM has this concern, which is based upon the  
6 current wording of the New Part 35.

7 We have some practical concerns. If a  
8 large enough pool of authorized medical physicists is  
9 not fully grandfathered, that is, authorized medical  
10 physicists, a shortage of NRC qualified medical  
11 physicists will result, which will negatively impact  
12 on patient care, as there will not be enough  
13 authorized medical physicists to deliver the needed  
14 services.

15 With an inadequate number of grandfathered  
16 AAMPs, the initial capacity of the NRC's preceptor-  
17 based system will be severely constrained,  
18 exacerbating the shortage of AMPs, and negatively  
19 impacting on patient care.

20 It appears from the responses to the  
21 public comments that only currently licensed  
22 teletherapy or gamma knife, or HDR physicists, will be  
23 allowed to precept trainees in teletherapy, gamma  
24 knife, or HDR, respectively.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1           Especially for teletherapy units and gamma  
2           knives, there are relatively few institutions and  
3           relatively few physicists to oversee and certify this  
4           training.

5           The cost to receive vendor endorsed gamma  
6           knife training is approximately \$5,000 for one week.  
7           The cost of preceptor based system may be substantial  
8           given the limited number of opportunities and training  
9           to obtain this training and experience.

10          The cost of solutions we wish to bring to  
11          your attention. One, revise 35.51 to make board  
12          certification in therapeutical radiological or  
13          radiation oncology physics a sufficient condition to  
14          serve as an authorized medical physicist.

15          Solution Two. Interpret 10 CFR 305.57  
16          broadly, which would create a grandfathered population  
17          of authorized medical physicists authorized to  
18          practice clinical physics for any 35.400 or 35.600  
19          modality, and to perform the preceptor function,  
20          regardless of the current modalities authorized on the  
21          license.

22          Possible Solution Three. Define a  
23          classification of authorized medical physicists who  
24          are authorized to manage the licensee's physics and

1 safety commitment for selective by-product material  
2 modalities.

3 The current wording for the New Part 35  
4 appears to require training and experience in all  
5 modalities, as opposed to a subset of modalities.

6 I wish to thank the ACMUI for considering the possible  
7 concerns and solutions.

8 The AAPM believes that these concerns are  
9 very important to ensure that the New Part 35 can be  
10 implemented successfully and that patients continue to  
11 receive therapeutic benefits from by-product materials  
12 in a safe and effective manner.

13 My third message is that the AAPM is  
14 prepared to work with the NRC staff to develop  
15 regulatory guides and force manuals for the New Part  
16 35 to ensure clarification of these concerns. Thank  
17 you.

18 MR. AYRES: If I could. Dr. Gillin  
19 brought up one issue, and to clarify that, that there  
20 is the grandfathering and everybody -- irrespective of  
21 what the final position is on board certifications,  
22 everyone who is currently an authorized user or  
23 authorized medical physicist, or authorized  
24 radiopharmacist, et cetera, will be grandfathered.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1           And so it is not an issue of coming out of  
2           the gate. There are some related ones, and his first  
3           suggestion looked like it would require a rule making.  
4           I think the grandfathering will be fairly broadly  
5           interpreted, but that's my position, and not an  
6           official one at this point.

7           CHAIRMAN CERQUEIRA: Okay. Jeffrey, you  
8           had some comments.

9           MR. WILLIAMSON: Yes. Could you explain  
10          the public comment in the OMB package which implies a  
11          contrary message to what you just said?

12          MR. AYRES: Public comments?

13          MR. WILLIAMSON: There is an 800 page  
14          document that went to OMB, the vast majority of which  
15          is responses and summaries of responses to public  
16          comments.

17          And in the public comments, that is where  
18          this concern is raised. It basically says that it  
19          will be interpreted to allow grandfathering only in a  
20          very specific modality driven way.

21          MR. AYRES: Well, clearly, we would not  
22          grandfather a 35.400 position authorization to include  
23          35.600 and 35.300 unless they were already listed.

24          MR. WILLIAMSON: Well, there you are.  
25          That's not being interpreted broadly.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 MR. AYRES: Well, I am looking at it in  
2 more of a -- well, the more narrow issue is how do we  
3 grandfather somebody that is listed as a -- and I am  
4 not saying that we don't have the answer right now,  
5 but a medical physicist who is listed as a teletherapy  
6 physicist, and not as a medical physicist, because we  
7 really didn't have that in the old Part 35.

8 We established it under guidance for HDR  
9 and gamma knife, and there is the possibility there to  
10 recognize any form of medical physicist, meaning to  
11 grandfathering him as a general medical physicist. I  
12 don't know where that will end up at.

13 MR. WILLIAMSON: Well, if you read the  
14 wording of 35.57 literally, it gives you the authority  
15 to do that. It basically says that anybody that is  
16 mentioned as a medical physicist or teletherapy  
17 physicist on a license without qualification need not  
18 satisfy the requirements of 35.51, period.

19 MR. AYRES: And I think that is what my  
20 remarks were about broadly.

21 MR. WILLIAMSON: And that is the position  
22 that Dr. Gillin is articulating, is to provide a pool  
23 of personnel to basically allow the conduct of current  
24 radiation oncology treatments.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1                   MR. AYRES:    And I think that is the  
2                   direction that we will probably get. The other issue  
3                   that you raised and that I thought about for a minute,  
4                   is that you asked for radiopharmaseuticals. We don't  
5                   require medical physicists for radiopharmaseuticals.

6                   MR. WILLIAMSON:   That was the question,  
7                   excuse me, about radiation oncologists. I wasn't  
8                   asking it about medical physicists.

9                   CHAIRMAN CERQUEIRA:   I think we should  
10                  stay on the medical physicists.

11                  MR. AYRES:    And as far as medical  
12                  physicists doing work in radiation and in  
13                  radiopharmaseuctical therapy, we don't require them.  
14                  They can do the functions they see fit there.

15                  CHAIRMAN CERQUEIRA:   I would like to get  
16                  comment from our two radiation oncologists about these  
17                  issues, and sort of get their input. David.

18                  DR. DIAMOND:   Yes. Dr. Gillin, first I  
19                  have a question for you. One of the solutions that  
20                  you proposed sort of implied or stated that perhaps a  
21                  mechanism whereby there would be different levels of  
22                  qualification could be entertained.

23                  That sounded very similar to what Bob  
24                  mentioned during his earlier discussion, where for  
25                  example, the individual would be recognized for all

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 entities, except for gamma stereotactic surgery, or  
2 accept for, or is that something that you think is a  
3 workable solution that you would be happy with as a  
4 means of making all parties satisfied without review  
5 of the rules making process?

6 DR. GILLIN: Yes, that is a solution. I  
7 was distressed in Dr. Ayres' presentation to learn  
8 that that has to go legal review to see if that is an  
9 acceptable interpretation.

10 MR. AYRES: Unfortunately, what the rule  
11 says is all, and so you clearly have to go to our  
12 Office of General Counsel to see if we have that  
13 options.

14 CHAIRMAN CERQUEIRA: Dr. Nag, do you have  
15 any comments on this issue?

16 DR. NAG: Yes, I think some of your issues  
17 fail. The part about the physicist who is well  
18 qualified with the internal -- most of that would  
19 really be similar to the cobalt 60, in terms of  
20 planning. You only actually need to know that and  
21 that is not a problem.

22 The issues with HDR are somewhat different  
23 than someone who is using external means, and there I  
24 don't think you can extrapolate the experience  
25 directly. But I do agree that your external -- and

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 your cobalt 60 would be very similar, and be  
2 extrapolated.

3 CHAIRMAN CERQUEIRA: Jeffrey.

4 MR. WILLIAMSON: I would just like to  
5 emphasize again the seriousness of the implications of  
6 a literal interpretation of the regulations as  
7 written, and if it partial AMP-ship is not recognized  
8 in any form whatsoever, there isn't going to be  
9 anybody to provide services for radiation therapy  
10 literally.

11 I think implementation of the regulations  
12 would require essentially facilities to shut down and  
13 cease offering these services. This is a very serious  
14 issue, and to have this sort of hanging by a legal  
15 thread, I think to make this rest on such a sort of  
16 ridiculous issue I think certainly -- well, if a  
17 negative legal decision is reached in this matter,  
18 this alone might be grounds for considering to table  
19 the implementation process until the wording can be  
20 changed. That's certainly one option.

21 MR. AYRES: I guess the comment here is  
22 that a lot of comments are coming about the rule  
23 language that would be passed, and unfortunately these  
24 would have been very valuable when the committee was

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701



1 working on this several years ago, and there was a  
2 chance to change it.

3 MR. WILLIAMSON: Well, I think everybody  
4 has to bear some responsibility for this. I don't  
5 think anybody either on NRC's side or in the regulated  
6 community that participated in the response to these  
7 regulations imagined this would happen.

8 But now it has happened, and so it seems  
9 that it is not a wise course of action for a  
10 regulatory agency to rigidly pursue a disastrous  
11 course of action.

12 MR. AYRES: Well, as a staff, we have to  
13 pursue what the rule says.

14 CHAIRMAN CERQUEIRA: Right. Let's get  
15 comments from Richard, then John, and then Naomi.  
16 Richard.

17 DR. VETTER: I would just like to echo a  
18 comment that Dr. Gillin made to long term  
19 implications, and I realize that there is no short  
20 term fix for this. But the current or the proposed  
21 Part 35 in no way encourages certification.

22 It doesn't prevent qualified people from  
23 becoming qualified medical physicists or radiation  
24 safety officers, but in fact it does not encourage

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 board certification. Now, I know that is not NRC's  
2 purview to go out and try and get people certified.

3 But in terms of long term public health  
4 and safety, which Dr. Gillin mentioned, we should be  
5 encouraging people to become board certified. And so  
6 relative to focusing down the road here on perhaps how  
7 language should be changed, I think that should be  
8 kept very high in consideration.

9 CHAIRMAN CERQUEIRA: John.

10 MR. AYRES: I think our intent was to  
11 maintain what Dr. Gillin said, was that the board's  
12 established level of expertise would be acceptable,  
13 and somehow we got a little bit amiss there. We got  
14 a disconnect.

15 But at least we have flexibility of taking  
16 the board certifications out of the rule to work with  
17 them perhaps a little bit more than we would have  
18 under the old rule. I think Cathy had something to  
19 say.

20 CHAIRMAN CERQUEIRA: Well, let's have  
21 John, Naomi, and then Cathy. John.

22 MR. GRAHAM: Well, I need some  
23 clarification, and this may need clarification from  
24 the OGC. When we sat here and discussed this, clearly  
25 the intent was that if there were certification boards

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 that were existing that covered the training that was  
2 reasonable and prudent for the protection of the  
3 public safety, that it was the most expeditious route  
4 for us to take to make sure that the adequate training  
5 had been covered.

6 And as I read this thing, it says that the  
7 licensee shall require the authorized medical  
8 physicist to be an individual who, (a), is certified  
9 by a specialty board whose certification process  
10 includes all of the training and experience required  
11 in paragraph (b) of this section, and whose  
12 certification has been recognized by the Commission or  
13 an agreement State.

14 Then if you go on to read literally  
15 paragraph (b), it says that you have to hold a Masters  
16 Degree or a Doctor's Degree in physics by a physics  
17 radiologic, physics medical, et cetera.

18 And then it goes on to state that you have  
19 to have an additional year of full-time work  
20 experience under the supervision of an individual who  
21 meets the requirements for an authorized medical  
22 physicist at a medical institution that includes the  
23 tasks listed in, and then it runs all the way from  
24 35.67 through 35.652, as applicable.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1           And that word would tie back to the board  
2           certification as it was discussed here, as applicable.  
3           And that then, two, has obtained written certification  
4           that the individual has satisfactorily completed the  
5           requirements in paragraph (b)(1) of this section, and  
6           has achieved a level of competency sufficient to  
7           function independently as an authorized medical  
8           physicist for each type of therapeutical medical unit  
9           for which the individual is requesting authorized  
10          medical physicist status.

11           The way we wrote this rule and had it set  
12          up was so that the boards could be a de facto partial  
13          certification. Am I hearing a legal interpretation  
14          from the OGC that their reading this literally to be  
15          all-inclusive?

16           MR. AYRES: No. The way I am reading it  
17          as a staff member, is that we have to take it to OGC  
18          is the all overrides as applicable.

19           MR. GRAHAM: Why?

20           MR. AYRES: Because the all applies to  
21          board certification and the applicable provides for  
22          coming in for authorization on the basis of training  
23          and experience. Now, this is not a resolved issue,  
24          and this has to go to OGC.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 MR. GRAHAM: Well, let me just finish my  
2 comment, because I am just about done. Clearly the  
3 intent through hour upon hour of discussion with this  
4 group making recommendations to the condition, or to  
5 the Commission, was that the board certification,  
6 having been reviewed by that body as being a  
7 reasonable and prudent approach to assure for the  
8 public safety would be accepted.

9 So to now say that the word all has gone  
10 from being where applicable, and where it has been  
11 requested, to where you have got to know everything  
12 from soup to nuts, is defeating the purpose of why we  
13 tried to use board certification as the most  
14 expeditious process to get this moving forward.

15 So I think we have taken one word, and it  
16 is unfortunate that we are inside the beltway and that  
17 it seems to take on glaring focus in testimony on what  
18 is the definition of that word was. That was not the  
19 intent as we sat here.

20 And I would like somebody on the committee  
21 to clarify if I misunderstood all of that way.

22 CHAIRMAN CERQUEIRA: In my having sat  
23 through all of these discussions that was clearly our  
24 intent. let's get a comment from Naomi, Cathy, and

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1       then perhaps the counsel could give us an  
2       interpretation as well.

3               DR. ALAZRAKI: I would like to thank Dr.  
4       Gillin for his statement. I think it was very -- an  
5       important statement, and it brings to attention the  
6       issue of the boards and not disenfranchising boards  
7       with this licensing process.

8               I also, as Dr. Gillin indicated in his  
9       statement, there are broader implications to that  
10      statement, which extend into other areas other than  
11      the medical physics area.

12              And just as a broad guideline type of  
13      statement, what I would like to say is that it is  
14      very important that the NRC match their licensing to  
15      the training and qualifications as exhibited by board  
16      certification.

17              And this may take more scrutiny than I  
18      think is being applied right now, and a little bit  
19      more of a breadth of understanding of what the  
20      training is, and what they are applying for.

21              For example, the business of the nuclear  
22      cardiologist becoming an RSO for all of nuclear  
23      medicine makes no sense at all, or of an individual  
24      not trained or experienced in handling some  
25      radionuclides being licensed to do that.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 CHAIRMAN CERQUEIRA: Cathy, you wanted to  
2 make a comment?

3 MS. HANEY: Well, actually, just a  
4 question for Dr. Gillin. In order to sit for the AAPM  
5 certification do you need any --

6 DR. GILLIN: The AAPM does not certify.

7 MS. HANEY: Okay. Do you need to have any  
8 practical experience or will just the fact that you  
9 have a Masters Degree allow you to sit?

10 DR. GILLIN: To the best of my  
11 recollection, practical experience is needed.

12 MR. WILLIAMSON: Yes.

13 MS. HANEY: But it is not specified in the  
14 --

15 DR. GILLIN: To the best of my  
16 recollection, it is specified, but I don't recall  
17 exactly how long.

18 MR. AYRES: I have it here if you want to  
19 talk to me Cathy later about it.

20 MS. HANEY: Okay.

21 MR. AYRES: Remember that there are also  
22 two boards in medical physics.

23 DR. GILLIN: Correct, and practical  
24 experience is needed for both boards.

25 MR. AYRES: Yes.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 MS. HANEY: So the issue really is that  
2 the practical experience may only be in one modality  
3 and not cover, let's say, all three?

4 DR. GILLIN: Correct.

5 CHAIRMAN CERQUEIRA: Jeffrey.

6 MR. WILLIAMSON: Well, I think Dr.  
7 Gillin's presentation highlights at least three  
8 different levels of issues that could be made in the  
9 form of recommendations of this committee to the ACMUI  
10 on how to proceed.

11 I think the third one that he made was  
12 really important, and it really has not been mentioned  
13 much here, and that is to basically for the NRC staff  
14 to work carefully with expert consultants or  
15 volunteers from the regulated community to draft  
16 realistic guidelines for supplementary training for  
17 somebody that is board certified, and say only has  
18 limited experience; either a radiation oncologist or  
19 a medical physicist candidate, but not specific  
20 experience with Cobalt 60 teletherapy.

21 I think that this is something that the  
22 NRC cannot do by itself, and it needs the scientific  
23 and clinical input of the community. So I would  
24 recommend that the NRC staff adopt a sort of  
25 subcommittee based approach similar to what we went

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701



1 through when we participated in the revision of the  
2 regulations, to develop realistic guidance for  
3 implementing supplementary training standards needed  
4 to implement the rule as written.

5 So that would be one recommendation or  
6 maybe a motion that I would make.

7 MR. AYRES: I think a lot of that is in  
8 the hands of this committee. As you know, when we  
9 have an issue like that, we bring it to the committee  
10 for their advice, and if they wish to set up a  
11 subcommittee of individual specialties, rather than  
12 the committee in its entirety, to provide this  
13 guidance to us when we bring these issues to you,  
14 that's in your hands.

15 MR. WILLIAMSON: So I make that as a  
16 motion.

17 CHAIRMAN CERQUEIRA: So restate your  
18 motion then.

19 MR. WILLIAMSON: Okay. I move that the  
20 ACMUI recommend to the NRC staff that a subcommittee  
21 based approach be developed to involve appropriate  
22 ACMUI members into the sort of detailed -- the  
23 formulation of a detailed supplementary training  
24 standards needed to certify physicists and authorized  
25 users on a modality by modality basis.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 I should say a supplementary training on  
2 top of board certification, and that needs to be  
3 inserted. John is so good at reading this that I  
4 would ask him to try and help me get it into shape.

5 CHAIRMAN CERQUEIRA: Do we have a second  
6 on that?

7 DR. VETTER: I second.

8 CHAIRMAN CERQUEIRA: And discussion?

9 DR. DIAMOND: I have discussion. So,  
10 Jeff, if I understand you correctly, you are trying to  
11 propose a mechanism whereby these individuals can in  
12 a supplementary fashion, and in an efficient fashion,  
13 meet the full requirements as outlined according to  
14 the rules.

15 And what I would like to come back to and  
16 ask do you favor that type of an approach or do you  
17 favor the approach that I was questioning earlier,  
18 which is to simply go and have categorizations, such  
19 as recognized RSO versus some partiality, where an  
20 individual who is never going to see a Cobalt unit in  
21 their life need not go through three days of training  
22 on Cobalt units to do it?

23 MR. WILLIAMSON: Well, I don't think that  
24 can happen in the 12 months or so we have to implement  
25 this regulation. Basically, what you are proposing

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 would require the board certification organizations to  
2 basically redo their entire framework to basically  
3 offer certificates or board certification that is  
4 modality specific, and would specifically state Cobalt  
5 60 teletherapy, or HDR, and so on.

6 DR. DIAMOND: It is more along the lines  
7 of thinking that there would be a mechanism that when  
8 an individual is petitioning NRC to enter the license  
9 as an RSO that he or she could go and say RSO, except  
10 for the following responsibilities, and that there  
11 would be a mechanism to have that approval.

12 MR. WILLIAMSON: The essence of board  
13 certification is that it is sort of automatic. You  
14 have board certification that is prima facie  
15 equivalent to being an authorized medical physicist,  
16 and that would allow a specific scope licensee to  
17 immediately hire and to allow to begin work a medical  
18 physicist or radiation oncologist without further  
19 investigation.

20 If that condition is not met in this  
21 automatic way, they have to proceed by license  
22 amendment, and have this individual's specific  
23 credentials reviewed. And I think unless the board  
24 reviews the credentials in a sort of automated --

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 DR. DIAMOND: So you are talking about  
2 approval by default essentially.

3 MR. WILLIAMSON: That's right, but I think  
4 to the extent that this method can be applied, I think  
5 it falls in what I said. What I am basically saying  
6 is let's be realistic. We are going to have to live  
7 with the wording of these regulations most likely.

8 So I think it is important for the  
9 community to try and work with the NRC staff to  
10 develop a set of guidelines that will allow radiation  
11 medicine to continue to be practiced basically without  
12 disruption, and I don't believe that they have the  
13 resources or knowledge base to undertake this  
14 themselves.

15 And I don't think that these one day  
16 committee meetings allow sufficient input and  
17 discussion time, and --

18 DR. DIAMOND: To deal with those details,  
19 but I --

20 MR. WILLIAMSON: -- that a subcommittee is  
21 necessary.

22 CHAIRMAN CERQUEIRA: You know, when you  
23 create subcommittees, you are adding more work. I  
24 think the intent of the ACMUI all along was to take  
25 board certification as an approval mechanism. I guess

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 I don't know enough about the -- and the issue has  
2 come up with whether teletherapy, gamma knife, or HDR,  
3 are sufficiently different in terms of the risks that  
4 you are going to need specific experience.

5 MR. WILLIAMSON: I was going to make other  
6 proposals to govern that, and to speak to that issue.  
7 I'm sorry to interrupt.

8 CHAIRMAN CERQUEIRA: Well, if there is no  
9 issue, and if the radiation oncologist and the people  
10 that are involved feel that the training in one is  
11 sufficient to extend to the other, then I don't see  
12 that as an issue.

13 But if there are some concerns that if you  
14 are using -- you know, if you need specific training  
15 in the one area, then it may not meet the language  
16 exactly. But, Dr. Nag.

17 DR. NAG: I think the staff, the NRC  
18 staff, is -- well, there are two different issues.  
19 One is the radiation risk issue, and the other is a  
20 medical issue about the use of that sub-modality. The  
21 medical issues are different between the three  
22 modalities.

23 But the radiation risk issues overlap, and  
24 therefore I think that for the NRC to say that we are  
25 making these rules because you have training in one,

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 but not in the other, and therefore you cannot  
2 practice that modality, you are infringing on the  
3 medical issue.

4 But the risk issue at the same time, I  
5 think for the NRC's purpose, there really shouldn't be  
6 a differentiation. If you are board certified in  
7 radiation oncology, you would have the ability to  
8 practice all of those.

9 Now, for the medical issue, that I think  
10 is an issue for the hospital and if you have a  
11 radiological machine, you go through training that is  
12 recommended by the manufacturer.

13 If you have an gamma knife, even though I  
14 am board certified, I am not allowed to handle a gamma  
15 knife unless I go to through the training for the  
16 gamma knife. So that is a medical issue.

17 So I think from the NRC's point of view,  
18 board training or board certification should apply to  
19 all of them, and then medically if you have to use  
20 them, you have other medical issues and other medical  
21 certification that you have to go through to use that.

22 CHAIRMAN CERQUEIRA: I think enforcement  
23 may be an issue there. David, did you feel that the  
24 risk is comparable between the three, and somebody who

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 is trained in one has sufficient knowledge to deal  
2 with the risks of all three?

3 DR. DIAMOND: I think it would be  
4 inappropriate for an individual just with training  
5 with linex (phonetic) just to without any additional  
6 training to start overseeing a gamma knife  
7 radiosurgery program.

8 I think what we are focusing on here is  
9 that since only a minority of practices in the country  
10 have this technology, is there a need to require all  
11 applicants to go and proceed with that. Subir's point  
12 was, well, gee, if I am applying to be an RSO, it  
13 would make sense that the entity or the hospital would  
14 not go and support my petition if I am not qualified  
15 to do that.

16 But that would put the institutions  
17 perhaps in a little bit of an uncomfortable position.

18 CHAIRMAN CERQUEIRA: Ruth, how do you  
19 think the agreement States would deal with this issue?

20 MS. MCBURNEY: I think for the medical  
21 physicist, and for the authorized user, we would want  
22 to see some additional training, even if it is just  
23 what is required by the manufacturer, and we would  
24 like to see that.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 MR. AYRES: You are really talking about  
2 what we do now.

3 MS. MCBURNEY: Right.

4 MR. AYRES: Which is that we have a  
5 narrower certification and then we require the  
6 specific training and experience to add the additional  
7 authorization.

8 MS. MCBURNEY: But for gamma knife, or the  
9 --

10 MR. AYRES: But that isn't what got put  
11 into the requirements for the new part 35.

12 CHAIRMAN CERQUEIRA: Well, if we are  
13 focusing on the issue aspects, if there is no safety  
14 issues, and again if the knowledge base is the same,  
15 then I don't see it as quite as much of an issue.

16 And I am still having a little bit of a  
17 problem. You know, David seems to feel that there are  
18 different risks.

19 MR. AYRES: I guess in summary that I  
20 think the NRC and this committee, and the  
21 stakeholders, all want to achieve the objective that  
22 you are talking about of the recognition of the  
23 boards, and then the actual implementation of the  
24 language. We seem to have a little disconnects as to  
25 that.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701



1 CHAIRMAN CERQUEIRA: We need to wrap this  
2 discussion up, but we still have a motion. Let's have  
3 several more comments for discussion and then we  
4 should either take a vote or move on.

5 MR. WILLIAMSON: Well, I would like to  
6 comment that I think we are confusing two issues here.  
7 One issue is basically whether board certification in  
8 a field like radiation oncology or medical radiation  
9 oncology physics is sufficient to be an independent  
10 practitioner, and is a reasonable grounds for assuming  
11 that the professional has sort of sufficient  
12 intellectual equipment and experience to be able to go  
13 and get the necessary training and experience, and  
14 read the appropriate papers, do the necessary  
15 supervised and unsupervised self-practice, to be able  
16 to deal with novel modalities or clinical situations  
17 that they have not encountered.

18 And I think the answer is yes, and I would  
19 -- and I think we should speak to that in a separate  
20 motion. My motion is a very -- speaks to the sort of  
21 political and regulatory reality that we have.

22 We have this regulation, and I think there  
23 is a very high chance that it is not going to be  
24 changed, no matter what we say. At least, soon. So  
25 I am proposing a mechanism whereby the community can

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 influence in a positive way I think the supplementary  
2 guidelines that are going to obviously be mandated in  
3 order to meet the letter of the new law.

4 And I don't want to give the impression  
5 that I personally, or that the professional  
6 associations that I am involved with, are not in favor  
7 of extra training for new modalities.

8 Of course, we seek out the appropriate  
9 training that we need to do novel things as  
10 professionals who are -- well, as competent  
11 professionals would in any field. So that is not the  
12 issue.

13 So I think to try and make these  
14 supplementary guidelines as close to clinical reality  
15 in what we do now is what the intent of this is.

16 And to speak to the sort of more  
17 philosophical concerns, I would propose another motion  
18 which I will make when you are ready to entertain it.

19 CHAIRMAN CERQUEIRA: Well, we should  
20 proceed. John, you had a last comment, and then we  
21 should call a vote.

22 MR. GRAHAM: Jeffrey, I guess the concern  
23 that I have got with this whole subcommittee concept  
24 is that we are just introducing another layer of  
25 bureaucracy, and in which as we sit here we were

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 desperately trying to avoid when the discussion first  
2 came up.

3 So let me suggest -- and you have a motion  
4 on the floor, and so it is moot, but this committee  
5 may want to consider something to the effect that the  
6 ACMUI considers board certification as a favorable  
7 process for improving the quality of training and  
8 practice of a profession.

9 And for the purpose of implementation of  
10 the proposed revision of 10 CFR Part 35, it is  
11 recommended that the interpretation of the condition  
12 that the certification process includes "all" of the  
13 training and experience, is limited and/or partial  
14 authorization, as modified by the applicability,  
15 and/or requested status.

16 I don't think we have to change the rules.  
17 I think it is already in there as to how you interpret  
18 that.

19 MR. WILLIAMSON: I don't think we need to  
20 change the rules. I am talking about guidance, and  
21 so, no, that is not my motion at all.

22 MR. GRAHAM: I know, but I am recommending  
23 in lieu of subcommittees, that if we just send up the  
24 clarification that all is governed by the restrictive  
25 language in paragraphs (b), that we have gotten to the

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 intent that board certification was the path of least  
2 resistance to get where we needed to be on  
3 documentation of training.

4 MR. WILLIAMSON: That is not allowed by  
5 the current rules and it just won't work. I was going  
6 to make another motion about that to cover the rule  
7 text and its need to be revised.

8 CHAIRMAN CERQUEIRA: We need to go on.  
9 Cathy, you wanted to make a comment.

10 MS. HANEY: I just wanted to make a point.  
11 The Committee has used subcommittees before. It was  
12 in the early '90s when we were working on 35.75, and  
13 we also used it during the rule making on 35 in the  
14 nitty-gritty rule text, where we sat down with  
15 subcommittees, and we meant diagnostic and therapy.

16 And then what happens is that we work  
17 things out with the subcommittees, and then we come  
18 back to the full committee, and make the  
19 presentations, basically a briefing on what the  
20 subcommittee decided.

21 CHAIRMAN CERQUEIRA: Could we get sort of  
22 counsel's opinion on this, Marjorie?

23 MR. AYRES: I think she has left. I  
24 wouldn't --

25 CHAIRMAN CERQUEIRA: No, she is here.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 MR. AYRES: Oh.

2 CHAIRMAN CERQUEIRA: I would agree with  
3 John that if we start adding subcommittees that it  
4 gets into a much more complicated process. If it is  
5 felt that there may be specific training in these  
6 modalities, should that be handled at the local site.  
7 That would be the simplest way.

8 MR. AYRES: I would add that as a  
9 procedural matter of having dealt with this for a long  
10 time just quickly, that you as chairman, and your  
11 predecessors, have really used sort of a subcommittee  
12 system.

13 We referred the training and experience  
14 issue to you, and you sent it to the appropriate  
15 members with expertise in that area for their  
16 feedback, and of course when we get the committee's  
17 opinion in writing by e-mail or whatever, it goes into  
18 our databases as to that.

19 CHAIRMAN CERQUEIRA: But that goes to the  
20 complexity, which is part of what we wanted to do,  
21 which was to simplify. Marge, we have asked you to  
22 stand up. So we have to get your comments.

23 MS. ROTHSCHILD: I will provide my  
24 comments. I would just like to say that the issue  
25 having been raised with the staff, that I would expect

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 the staff to use as it usually does, or always does,  
2 its best efforts to resolve this.

3 And that could include consulting with OGC  
4 if the staff deems it necessary. So I would expect  
5 the usual practice would be followed here.

6 MR. AYRES: Yes.

7 MR. AYRES: Jeffrey.

8 MR. WILLIAMSON: Okay. I think the issue  
9 that I am trying to address is the formulation of  
10 licensing guidance. The specific criteria of if you  
11 are a board certified physicist, for example, but have  
12 not been trained on cobalt 60 teletherapy, how many  
13 hours of training and experience do you need on top of  
14 an extensive base of linac experience to become an  
15 authorized medical physicist.

16 How many cases of HDR, and they could  
17 require 500 hours of HDR training and that would be  
18 ridiculous and impossible. So the intent of my  
19 recommendation is to basically recommend to the NRC  
20 staff that they involve the appropriate  
21 representatives on this committee -- and I mean those  
22 that specialize in the modalities in question in the  
23 detailed nitty-gritty negotiation of these  
24 supplementary criteria are.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1           It is not an attempt to create more  
2 complexity for you and the organization of this  
3 committee. It is basically recommending to the NRC  
4 that they need to involve representatives of the  
5 community who have the technical expertise and  
6 clinical experience to help formulate these guidelines  
7 in a way that is both workable and safeguards public  
8 safety.

9           So I just don't think it can be left to  
10 some imaginary local site or to you, yourself, with  
11 all due respect. So I think it is extensive off-line  
12 conversation that cannot be achieved in a short period  
13 --

14           CHAIRMAN CERQUEIRA: Well, why don't you  
15 restate your motion, and we should vote on it.

16           MR. WILLIAMSON: Okay. The ACMUI  
17 recommends to the NRC staff that they involve  
18 qualified members of the ACMUI in the detailed  
19 discussions leading to the formulation of  
20 supplementary training requirements that will allow  
21 board certified radiation oncologists and medical  
22 physicists to become authorized medical physicists and  
23 authorized users in modalities in which they lack the  
24 specific training and experience thereof.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 CHAIRMAN CERQUEIRA: Okay. So a motion  
2 has been proposed and discussed. We will call for a  
3 vote. All those --

4 MR. GRAHAM: Well, we didn't get support  
5 of that motion, and we never took the old motion off  
6 the table.

7 CHAIRMAN CERQUEIRA: I just asked him to  
8 restate it. Do we want a second on that?

9 MR. WILLIAMSON: Okay. I withdraw the  
10 first motion and put this one on the table then.

11 DR. NAG: A slight modification.

12 CHAIRMAN CERQUEIRA: Okay. So, yes.

13 DR. NAG: You are saying only members of  
14 the ACMUI. For example, if we don't have members of  
15 the ACMUI who have expertise in that certain subject  
16 area, it should be members of the ACMUI or a  
17 specialist.

18 MR. WILLIAMSON: Okay. I think that's  
19 fair, or invited consultants.

20 CHAIRMAN CERQUEIRA: Okay. So do we have  
21 a second on the modified second?

22 DR. NAG: I second.

23 CHAIRMAN CERQUEIRA: Any further  
24 discussion on this? Cathy.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701



1 MS. HANEY: Just a notation that those  
2 meetings would have to be public meetings. So in the  
3 case where you said you didn't have someone with a  
4 specific specialty available, it would be in a public  
5 setting, and so the members of the public could be  
6 there, and I think that is getting at Dr. Nag's issue.

7 The other thing, too, is the way that Jeff  
8 has referred to supplementary information. You need  
9 to be very careful because you want all the  
10 requirements in the rule, and that is one thing that  
11 we have been preaching for the last three years; that  
12 there are going to be no de facto regulations and  
13 guidance documents.

14 And in my opinion the way that  
15 recommendation is worded right now, you could lead  
16 someone to believe that there is another set of  
17 criteria.

18 And I think what Jeff is really talking  
19 about is how the rule is implemented, versus coming up  
20 with supplementary criteria, and I think that is an  
21 important distinction for the record.

22 MR. WILLIAMSON: That certainly is a valid  
23 clarification.

24 MS. MCBURNEY: I have a question on that.

25 CHAIRMAN CERQUEIRA: Yes, Ruth?

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 MS. MCBURNEY: So there is going to be no  
2 additional guidance on how this is to be implemented?

3 MS. HANEY: Well, we have the new reg that  
4 is -- new reg 15.56, Volume 9, that basically tells  
5 you how to apply for a license in the medical area,  
6 and it has some model procedures in it for the  
7 different items.

8 But it is very clear in the document that  
9 those are strictly model procedures, and that there  
10 are no de facto regulations in there. It is one way  
11 of meeting it, that you can look to your professional  
12 organization for ways of meeting it.

13 So if from that standpoint, Ruth, yes,  
14 there is a guidance document. But from the standpoint  
15 of training and experience, we have tried very hard to  
16 stay away from a breakdown of the hours.

17 Like, for example, people have said that  
18 you said 500 hours, and if we only do 10 classroom and  
19 490 in the practical environment, are you going to  
20 accept that, and we have not commented on that at all.

21 So I do not envision us getting down to  
22 the point where we are saying X number of cases,  
23 observe one gamma stereotactic radiosurgery procedure,  
24 and you are okay; or observe two or this is the  
25 breakdown of hours, because that was one of the things

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1       that we tried to stay away from with this rule making,  
2       was to get at the prescriptive nature and leave the  
3       flexibility to the different organizations and the  
4       boards, and at the hospital level.

5               CHAIRMAN CERQUEIRA: I think this is a  
6       step away from that.

7               MS. HANEY: Well, it is not a step away  
8       because if you focus on the implementation of the  
9       rule, but if you are focusing it on the implementation  
10      for the purposes of breaking it down to case work  
11      level, then maybe that is somewhere where you don't  
12      want to go. And I don't think we are in disagreement,  
13      Jeff, are we?

14              MR. WILLIAMSON: Well, actually my intent  
15      if I were participating in such a discussion group  
16      with the NRC, would be to sort of oppose such highly  
17      prescriptive measures, and try to get something that  
18      is sort of realistic and general as possible.

19              MR. AYRES: I would just comment that Jeff  
20      conditioned his with board certified, and we do come  
21      into you with non-board certified T&E issues.

22              CHAIRMAN CERQUEIRA: Right. All right.  
23      Let me call for a vote. All of those in favor of the  
24      proposed motion?

25              (A show of hands.)

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 CHAIRMAN CERQUEIRA: Okay. Eight in  
2 favor. Opposed?

3 MR. GRAHAM: I have to oppose this one.

4 CHAIRMAN CERQUEIRA: Okay. One  
5 opposition. Abstention? Okay. So we have recorded  
6 a vote. Now, this brings up a whole lot of other  
7 issues. I can see that the cardiology community would  
8 now want to come back and propose some changes for  
9 some of these things, although let's go ahead with  
10 this.

11 There is a lot of spin-offs. I don't know  
12 if we should basically follow through with some of  
13 these others, or we should go on to the next item,  
14 which is the brachytherapy procedures not covered by  
15 the FDA approval.

16 What is the wish of the committee? Do we  
17 need further discussion or clarification on this?  
18 Jeff.

19 MR. WILLIAMSON: I was going to suggest  
20 another motion.

21 CHAIRMAN CERQUEIRA: Make your motion and  
22 I will entertain whether --

23 MR. WILLIAMSON: All right. Whereas, the  
24 ACMUI believes that board certification in an  
25 appropriate specialty adequately prepares physicists

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 to function safely as authorized medical physicists  
2 and radiation oncologists, the ACMUI recommends that  
3 the NRC staff undertake a rule making initiative as  
4 soon as possible to basically restore board  
5 certification as a sufficient condition for being an  
6 authorized user or authorized medical physicist.

7 DR. NAG: I don't think I understand what  
8 your intention is.

9 CHAIRMAN CERQUEIRA: Yes, and why just  
10 physicists? Why not all the others, and  
11 radiopharmacists and --

12 MR. WILLIAMSON: Because I am not sure  
13 that it is a problem for anybody else. If it is, I  
14 would certainly be adding them to the rule.

15 CHAIRMAN CERQUEIRA: Well, the  
16 clarification now has been that way. Lou.

17 MR. WAGNER: I don't think that is  
18 necessary, John Graham's interpretation of saying the  
19 rule doesn't need to be changed. We don't have an  
20 opinion from the Office of General Counsel yet on the  
21 interpretation of this rule.

22 And furthermore what we have just said is  
23 the following. That we have not changed the rule at  
24 all. The biggest problem that is being pointed out is  
25 that if you want to be certified in teletherapy, and

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 in stereotactic, or whatever, you need a year in each  
2 one of these.

3 The point is that there is a lot of  
4 overlap in the training. You don't need a year  
5 specifically in this and then a year in that, and then  
6 a year in that, because you can count what you have  
7 done in here in the training, and much of the training  
8 is an overlap.

9 You just need something that is  
10 supplemental to make sure that it adds up to a year  
11 for stereotactic, but it doesn't have to be a full  
12 year in it.

13 It just have to be that little  
14 supplemental thing, and he is just saying to use the  
15 expertise here to give advice to the NRC on how to get  
16 that. But don't go down to any more additional rule  
17 making, and don't do any of that stuff. That's all it  
18 is.

19 CHAIRMAN CERQUEIRA: I think I will take  
20 the Chairman's prerogative and just go on to the next  
21 issue. I would like to thank Dr. Gillin for his  
22 presentation, and we will go on to the next item,  
23 which is Authorization for Brachytherapy Procedures  
24 Not Covered by FDA Approvals by Donna Beth Howe.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1                   We can probably go until 12:00 on this  
2                   because we don't really need an hour and 15 minutes  
3                   for lunch, and if we don't cover it sufficiently, we  
4                   could or we have got some time in the afternoon where  
5                   we could make up for the time and continue the  
6                   discussion.

7                   MR. HICKEY: Mr. Chairman, this is John  
8                   Hickey. I just wanted to clarify that in connection  
9                   with this presentation there was a written document  
10                  provided to the committee by LeBoeuf, Lamb, Greene and  
11                  MacRae, representing the NOVOSTE Corporation, and  
12                  there are people here from NOVOSTE in case there is  
13                  any questions with respect to this issue.

14                  CHAIRMAN CERQUEIRA: Thank you, John.  
15                  Everybody should have the punched stabled, dated April  
16                  13th, and there was a copy of the letter wasn't there  
17                  somewhere in here?

18                  MR. HICKEY: Yes.

19                  (Brief Pause.)

20                  CHAIRMAN CERQUEIRA: All right. Dr. Howe  
21                  is all set up with her audio-visuals here, and she  
22                  will define the issue.

23                  DR. HOWE: Actually, I was thinking we may  
24                  be able to go to lunch early.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 CHAIRMAN CERQUEIRA: I doubt it. I doubt  
2 it.

3 DR. HOWE: My topic is the authorization  
4 for brachytherapy procedures. I have got "and devices  
5 that are not covered by the FDA." But I am going to  
6 be focusing on the procedures that don't have FDA  
7 approval at this point.

8 And what I would like to do is kind of  
9 give up --

10 CHAIRMAN CERQUEIRA: If we could turn up  
11 Dr. Howe's microphone. Thank you.

12 DR. HOWE: I am going to be focusing on  
13 the procedures that aren't covered by an FDA approval,  
14 and what I am going to try to do is to give a little  
15 bit of an oversight, kind of a philosophical look at  
16 it.

17 And this is an extension of what Bob Ayres  
18 discussed at the last ACMUI meeting. So we are just  
19 going to be looking for additional comments from the  
20 ACMUI.

21 The issue is should brachytherapy  
22 licensing authorizations strictly follow the FDA  
23 approved indications for use. And at the last  
24 meeting, the ACMUI in general supported broader  
25 authorizations.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701



1 Dr. Diamond talked and essentially  
2 supported a more limited use that was in align with  
3 the FDA approved indications for use. But in general  
4 the other members were going more to a generally  
5 supported.

6 And what we are going to be doing is  
7 essentially looking at the medical policy statement,  
8 and using it. The staff is currently working on  
9 developing a policy to address this issue, and we are  
10 going to be using the medical policy statement as a  
11 basis.

12 And if you look at your handout, you will  
13 see what I have done is that I have minimized the  
14 medical policy statement, number one, because that one  
15 is not as appropriate to this discussion as two, which  
16 is the NRC rule of not intrudent to medical judgments  
17 affecting patients, except as necessary to provide  
18 radiation safety to workers in the general public.

19 But really the most significant part of  
20 the policy statement is going to be statement number  
21 three, which is that the NRC will, when justified by  
22 the risk to patients, regulate the radiation safety of  
23 patients primarily to assure the use of radionuclides  
24 is in accordance with the physician's directions.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1                   So that is the particular policy statement  
2                   that we will probably be using as a basic foundation  
3                   as we develop our policy.

4                   Well, we were kind of here before. Back  
5                   in 1989, we had a petition for a rule making from the  
6                   Society of Nuclear Medicine and the American College  
7                   of Nuclear Physicians that said for the  
8                   radiopharmaceutical drugs, we were being too  
9                   restrictive.

10                  We were enforcing the FDA package inserts  
11                  for indications for use for therapeutical  
12                  radiopharmaceutical use, and preparation for both  
13                  diagnostic and therapeutic.

14                  And we had an interim final rule in 1990,  
15                  and if you look at the letter from the law firm, you  
16                  will see a reference to 1990. That was the interim  
17                  rule for radiopharmaseuticals, where we allowed  
18                  physicians to direct changes in the preparation of  
19                  radioactive drugs, and also allow physicians under the  
20                  practice of medicine to use radioactive therapeutic  
21                  drugs for other indications that weren't in the  
22                  package insert.

23                  And the basis for that was that the  
24                  package inserts represent a position that the FDA

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 makes that the drug is safe and effective when used  
2 for the indications in the package insert.

3 It doesn't say that the drug is not safe  
4 for any other purpose. It just says that it is safe  
5 for that purpose that they reviewed. So then in 1994,  
6 we published the final radiopharmacy rule, and we had  
7 many lessons learned under the radiopharmacy rule.

8 And the one that is most appropriate to  
9 our discussion today is that NRC authorization for  
10 radioactive drugs were not going to be limited to the  
11 FDA approved uses.

12 And one of the things that you should  
13 notice is that the 1994 radiopharmacy rule was a  
14 radiopharmacy rule. It was not a radiopharmacy and  
15 medical device rule.

16 And I will give you a little bit of  
17 history now as to why we did not expand it to devices.  
18 One of the other things that we did in the  
19 radiopharmacy rule was one of the major concerns was  
20 that if we had a broader authorization, it might  
21 appear as if the NRC was giving physicians permission  
22 to do something that the FDA might not agree with.

23 And so to resolve this issue, we added  
24 35.7 to the regulations that said nothing in this part  
25 relieves the licensee from complying with applicable

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 FDA, and other State and Federal, requirements  
2 governing radioactive drugs.

3 Now, what it also did is that it said that  
4 the licensee is responsible for being in compliance  
5 with applicable FDA and other State and Federal laws  
6 associated with radioactive drugs.

7 We did add devices at this point because  
8 there was no reason that this statement should be  
9 restricted only to drugs; because prior to this  
10 essentially what was happening was that the NRC was  
11 enforcing FDA package inserts which were not meant to  
12 necessarily be enforced in the way that we were doing  
13 it.

14 So we shifted the responsibility to the  
15 licensee. And what I would like to do is kind of give  
16 you a brief historical of where we were back in 1994  
17 with devices.

18 You have seen that we had the  
19 radiopharmacy rule for radioactive drugs. Well, in  
20 1994, we had essentially all of our medical devices  
21 that were being used for therapeutic uses,  
22 brachytherapy in particular, were coming through the  
23 traditional brachytherapy source and device approval  
24 sequence.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 For FDA that meant a 510(k) process, and  
2 at NRC there was the -- it was the NRC sealed source  
3 and device registry, but the agreement States are also  
4 feeding their information into this registry.

5 And so we had those two elements very  
6 tightly tied together. NRC or the agreement State  
7 would wait for FDA to issue the 510(k), and that was  
8 the means by which FDA allowed medical devices to be  
9 legally marketed.

10 And as soon as the 510(k) was issued, the  
11 agreement State or NRC would add the device to the  
12 registry. We would be working on the registry while  
13 the 510(k) process was going on.

14 And we are focusing primarily on today's  
15 discussion with proposed uses. Well, what was the  
16 situation with proposed uses under the 510(k)? Under  
17 the 510(k) the determination that the FDA made was  
18 whether the device was substantially equivalent.

19 The brachytherapy sources were  
20 substantially equivalent to sources and devices that  
21 were on the market prior to '76. So, it wasn't  
22 necessarily for them to end up with elaborate proposed  
23 uses.

24 A brachytherapy source was a brachytherapy  
25 source. Everybody understood that was going to be

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 used for some form of cancer treatment. So you did  
2 not have specific indications for use.

3 So you had that proposed uses could be  
4 general, and in some cases where the devices were  
5 obviously similar to something that was on the market  
6 prior to the medical device rule, you might not even  
7 have the proposed use to address, because it was  
8 understood what it would be for.

9 So what do we have that is different  
10 today. First of all, we have got a lot of emerging  
11 type technologies and new uses that didn't exist prior  
12 to '76, and you also have a new medical device rule.

13 We are a long ways from 1976, and so it  
14 didn't make sense to continually say, well, this is  
15 substantially equivalent to something back in '76. So  
16 now the FDA in some cases will require clinical trials  
17 prior to 510(k) approval.

18 That wasn't going on very much back in the  
19 '80s and the early '90s. And you also had FDA pre-  
20 market approval, and that's where your intervascular  
21 brachytherapy devices are coming through a PMA  
22 process.

23 None of the other devices came through  
24 PMA. The high dose radio after loader, 510(k); the  
25 gamma knife, 510(k). So this is the first device that

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 we have been seeing over here at the NRC that has come  
2 through the premarket approval process.

3 And there are some additional devices that  
4 are coming through from the FDA Humanitarian Device  
5 Exemption. Dr. Case at the last meeting talked about  
6 the theraspheres in the Yttrium 90 microspheres.

7 They are used for a very limited -- well,  
8 what might be considered an orphan disease. So their  
9 approval came through the FDA Humanitarian Device  
10 Exemption.

11 And so we are starting to see some really  
12 very, very specific indications for use. In your  
13 handout in the book, I have just given two. One is in  
14 the radiation treatment of a neoadjuvant to surgery or  
15 transplantation in patients with unresectable  
16 hepatocellular carcinoma.

17 We never saw anything like that before in  
18 the 510(k) process. The in-stent restenosis of native  
19 coronary arteries. We never had those kinds of  
20 specific proposed uses.

21 What we had had in the past -- and I am  
22 quoting from 35.400, and the most recent brachytherapy  
23 device added to 35.400, was in 1989, when the  
24 Palladium 109 was added.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1           And you will see that the uses are as  
2           sealed sources in needles, and applicator cells for  
3           topical, interstitial or intercavity treatment of  
4           cancer.

5           You may have like the Strontium 90 I-  
6           applicator for superficial I-conditions. So you had  
7           very broadly stated --

8           MR. GRAHAM: I'm sorry, but you made a  
9           reference that we had this in our packet.

10          MS. HOWE: No, you don't have this. This  
11          is in the regulation.

12          MR. GRAHAM: We are all desperately  
13          whipping through pages here trying to find it.

14          MR. AYRES: It is 35.400.

15          DR. HOWE: It is 35.400. I am just going  
16          from the regulation 35.400. So as you can see, in the  
17          old 35.400, the proposed uses were stated in very  
18          broad terms, and what we are seeing that is different  
19          today is we are getting devices that are approved  
20          through the FDA process with very, very specific  
21          indications for use. And that is one of our  
22          differences now.

23          Now, one of the other things that is in  
24          the current 35.400, 500, and 600, which are our  
25          medical device regulations, is that you have very

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701



1 broadly described uses, and these sectors cover not  
2 only routine clinical use, but also research uses.

3 And those research uses could either be  
4 because the device itself is investigational, or  
5 because an approved device is being used for some  
6 other research purpose.

7 So it is important to keep in mind that we  
8 are dealing with both routine clinical use and also  
9 research use. Okay. What was our licensing approach  
10 to some of the new devices, like the intervascular  
11 brachytherapy.

12 This is the first time that we were  
13 dealing with a device with a very specific proposed  
14 use. So initially when licensees came in and  
15 requested use of intervascular brachytherapy -- and in  
16 this case I am talking about the limited specific  
17 medical use licensees.

18 The broad scope licensees have a very,  
19 very broad authorization; medical research, and  
20 development, and treatment, diagnostic and therapeutic  
21 treatment.

22 So this has never been an issue for a  
23 broad scope. They have great latitude. So initially  
24 what the staff elected to do was that most of our

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 licensees that were limited specific were coming in  
2 and asking for exactly what was on the FDA approval.

3 And so while we were developing an overall  
4 policy to address some of the more difficult issues,  
5 the easiest way to get these authorizations out and  
6 let the physicians start using these new devices, was  
7 to approve the uses as limited to the FDA approved  
8 indications for use.

9 Now, today we are looking at and  
10 evaluating the broader use authorization, something in  
11 parallel to where we were with the radiopharmacy rule  
12 where you are allowing the practice of medicine for  
13 the new uses once you have got a legally marketed  
14 device.

15 And so that is currently under review, and  
16 what you -- and what we have done as a staff is that  
17 we have put out internal guidance to our licensing  
18 staff out in the regions, and that internal guidance  
19 was the limited approval based on the FDA recommended  
20 indications for use; in-stent restenosis of native  
21 coronary arteries for intervascular brachytherapy.

22 And now we are looking at revising that  
23 guidance and it is currently under review with the  
24 staff, and we have not gotten the new guidance out  
25 yet. Yes, Dr. Nag?

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 DR. NAG: Yes. I think we have to  
2 associate the laws of NRC and FDA. The laws of NRC is  
3 not to regulate the medical use, but to see to the  
4 radiation safety side.

5 For example, if you have a device, it may  
6 have a certain FDA approved use that is a medical use.  
7 The radiation safety consideration is if it were to be  
8 used for another reason.

9 And therefore that it is not the NRC's  
10 role to take and use it for (a), but not for (b). But  
11 we have to look to the radiation safety portion, and  
12 leave the medical use portion to the FDA. So I think  
13 we have to divide the radiation safety issue from the  
14 medical issues.

15 DR. HOWE: I think we will still maintain  
16 a broad description of the medical use in order to get  
17 it into the right category and ensure the right  
18 training and experience.

19 DR. NAG: Sure, but that is the Part 35 --  
20 well, where you say that nothing in this will -- you  
21 know, you still have to follow FDA regulations.

22 DR. HOWE: And I think that is the  
23 direction that we are intending to go, is to step back  
24 out of the specific FDA approval, but we still have to

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 keep it in a category that we can deal with for  
2 radiation safety purposes.

3 DR. NAG: Right. I would like to remind  
4 the staff to do that wording in such a way that they  
5 don't have to change the wording every time the FDA  
6 comes up with new uses of the same device, because the  
7 radiation safety issues are going to be the same.

8 CHAIRMAN CERQUEIRA: Comments. Jeff?

9 MR. WILLIAMSON: I wanted to point out one  
10 comment. You mentioned that these were new devices,  
11 and that had not gone through the 510(k) procedure  
12 before, and that's strictly speaking certainly not  
13 true.

14 For example, the best cordis product is  
15 the same interstitial brachytherapy seed that has been  
16 in widespread use for malignant indications since 1970  
17 approximately. So it is not a new product. It is  
18 sort of safety features that the issues of dose  
19 calculation, at least qualitatively speaking, are  
20 identical between the use in a malignant indication  
21 and a benign indication.

22 Now, of course, the FDA, because of the  
23 disease process being treated, required additional  
24 clinical trials to extend its use to that. But it  
25 does seem to me that that is sort of a medical issue,

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 and why would you want to get into it, and not just  
2 sort of leave it to the discretion of the individual  
3 physician and FDA, and other health oriented Federal  
4 agencies?

5 Why take it upon yourself to enforce  
6 something that FDA is not going to enforce. For  
7 example, whether you are going to use the Novoste  
8 source for treatment of in-stent restenosis treated  
9 with a 25 millimeter balloon instead of a 20  
10 millimeter balloon, are you going to -- well, that's  
11 the concern, and so how broadly or how narrowly are  
12 you going to restrict users to the specific clinical  
13 trial conditions under which the devices were  
14 developed. That's my question and you have heard my  
15 comment.

16 DR. HOWE: Yes, and I think the message I  
17 was trying to bring forth is that we are looking at  
18 the much broader use authorization and that's the  
19 direction that we are going into.

20 I can't speak specifically as to what it  
21 is going to be because we currently have that under  
22 review internally, but we are going to be, I believe,  
23 going to a much broader authorization than you have  
24 seen with what we initially did with our first license

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 authorizations, and we have not gotten that internal  
2 guidance out yet.

3 CHAIRMAN CERQUEIRA: It sounds like she is  
4 agreeing with you essentially, Jeffrey. David, did  
5 you want to make a comment?

6 DR. DIAMOND: Yes, I think we can get to  
7 lunch on time because at the last meeting six months  
8 ago I was in the minority position. Six months ago,  
9 my primary concern was that of the safety to the  
10 public about having a very rapid expansion to the  
11 number of brachytherapy procedures being performed in  
12 a situation where some of these procedures may be  
13 performed at anatomic sites, where there is absolutely  
14 no data to support its safety to the public.

15 My second concern six months ago was that  
16 by taking such a move that we would effectively  
17 extinguish some very important clinical trials that  
18 were midstream, because they would no longer receive  
19 the funding from the corporate entities to pursue  
20 them.

21 My thinking has changed since that  
22 meeting. Firstly, since our last meeting, there has  
23 been an increasingly amount of data suggesting that at  
24 least for the coronary arteries, and to a lesser  
25 extent the superficial feral artery system, that these

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 techniques when performed by appropriately trained  
2 teams of cardiologists, radiation oncologists, medical  
3 physicists, or as the case may be by interventional  
4 radiologists, that if nothing else, they appear to be  
5 safe in these settings.

6 So that primary fear that I had was laid.  
7 Secondly, as an individual who is kind of the  
8 director of a program where we are treating a very,  
9 very large number of patients, we face the constraints  
10 of how to treat individuals who are clearly in need of  
11 some type of modality, and that may not get this  
12 treatment without undue burden.

13 So perhaps to summarize my thinking, I  
14 would suggest that the staff of the NRC no longer  
15 instruct its stakeholders that FDA approved  
16 brachytherapy treatment devices, that the use of these  
17 devices -- excuse me.

18 That the staff of the NRC no longer  
19 instruct stakeholders that for FDA approved  
20 brachytherapy treatment devices that their use be  
21 limited to the FDA labeled indications alone.

22 In other words, I am trying to balance my  
23 concern for treating patients and getting this  
24 technology out there with my concern of potential  
25 harm.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1           In other words, the patient who has had 3  
2           or 4 in-stent restenosis involving a stent that is  
3           being graphed to a non-surgical candidate, that  
4           patient will die. That patient may die, and may die  
5           very soon unless we can try something.

6           We don't know clearly if it works long  
7           term, but certainly it appears safe. The safe thing  
8           could go for patients who may be at risk of losing a  
9           leg because of an SFA restenosis.

10          I say this with some trepidation, of  
11          course, because as soon as we go and move to this  
12          broader authorization, we could go and start having  
13          physicians, some of which have very little experience,  
14          start doing things that I would be very uncomfortable  
15          with, such as treatment of in-stent restenosis of the  
16          carotid circulation, or perhaps in-stent restenosis of  
17          the patient's tubular bacillar insufficiency.

18          But to try and weigh both of these things,  
19          I think we must go towards a broader use  
20          authorization. I would strongly encourage the  
21          professional societies to recommend to their members  
22          that if individuals or institutions wish to look at  
23          these different anatomical sites, that they be done on  
24          some sort of an IRB approved registry, or at least

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701



1 some sort of registry which was a mechanism six months  
2 ago and still is a mechanism.

3 But as you can see, my thinking has  
4 changed to some extent. So I would be willing to make  
5 a motion to that extent.

6 CHAIRMAN CERQUEIRA: I am not sure they  
7 are asking for a motion, and I agree with the general  
8 support, is that we -- you know, that the NRC and the  
9 ACMUI are dealing with radiation safety.

10 There is issues about ethicacy, which is  
11 really up to the FDA to deal with.

12 DR. HOWE: And the practice of medicine.

13 CHAIRMAN CERQUEIRA: And what?

14 DR. HOWE: And the practice of medicine.

15 CHAIRMAN CERQUEIRA: And the practice of  
16 medicine, and there is also issues about  
17 reimbursement; that if something is not clearly FDA  
18 indicated, HFCA may not pay for it. But that is not  
19 an issue that we need to deal with.

20 So I think we are supporting of what Dr.  
21 Diamond is saying.

22 DR. DIAMOND: I agree with you fully. My  
23 primary concern six months ago was the potential  
24 effect on public safety, and if we are releasing a  
25 huge volume of new procedures for which there was very

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 little safety data, if one excluded specific  
2 indications in the coronaries.

3 And again keeping with that same exact  
4 logic, with the data that we see emerging over the  
5 past six months, it forces me to modify my position as  
6 I iterated.

7 CHAIRMAN CERQUEIRA: Are there other  
8 comments? Dr. Williamson. Wagner, I'm sorry. The  
9 other physicist.

10 MR. WAGNER: I just wanted to go back to  
11 the medical use policy statement that I believe the  
12 NRC has adopted, which says that the NRC will when  
13 justified by risk to the patients regulate the  
14 radiation safety of patients primarily to ensure the  
15 use of radionuclides is in accordance with the  
16 physician's directions.

17 I think we have been down this road  
18 before, and I think the specific wording here puts us  
19 on very shaky ground. When they say to assure the use  
20 of radionuclides in accordance with the physician's  
21 directions, how do you define that?

22 We have been there before, and it is a big  
23 issue. It is a matter of what they think is in  
24 accordance, and what we think is in accordance. Two  
25 broadly different ideas.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 I think this wording here puts us on a  
2 dangerous track again, and frankly I think it should  
3 have been simpler, and say something like to ensure  
4 that the use of radionuclides is prescribed by a  
5 physician. Something very general.

6 But not something that says, well, was the  
7 dose delivered at this point, and what it was meant to  
8 be, and was it off by this much, and down the same  
9 doggone road. So I worry about this medical policy  
10 statement.

11 CHAIRMAN CERQUEIRA: Do you want to  
12 comment?

13 DR. HOWE: I guess with respect to my  
14 discussion, it appears to me that in this particular  
15 medical policy statement we are looking at the fact  
16 that we are recognizing the practice of medicine, and  
17 the physician can make the determination of how they  
18 want to treat the patient.

19 MR. WAGNER: I appreciate that effort, but  
20 I am just saying that the wording that you have got  
21 here is now revisiting a path that we have been down  
22 before, and where we run into problems with regard to  
23 interpretation.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 CHAIRMAN CERQUEIRA: Do you have  
2 suggestions for changing the wording, Lou, that would  
3 be more acceptable?

4 MR. WAGNER: I have just seen this, and so  
5 it is a matter that I didn't have a lot of time to  
6 think about it.

7 But I would say primarily to ensure the  
8 use of radionuclides is under the direction of a  
9 physician, period. It is under the direction of a  
10 physician, and it doesn't have to be specific about it  
11 is in accordance with the physician's directions.

12 Well, what does that mean? Does it mean  
13 the physician doesn't want to deliver a dose to a  
14 certain point, and he wants to put that in there, et  
15 cetera? Those are his directions. Well, if it is off  
16 by a little bit, is that outside those rules?

17 That is the thing that I want to get away  
18 from, and to simply say that the radionuclides are  
19 delivered under a physician's prescription.

20 DR. HOWE: Well, for these devices, you do  
21 have to have a written directive, and all we are  
22 looking for is that the procedure is given in  
23 accordance with the written directive.

24 MR. WAGNER: All right. So then the issue  
25 that I come to is they are going to regulate the

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 radiation safety of patients in accordance with this  
2 prescription again. To me, it is the same problems  
3 that we have revisited before.

4 I don't wish to make an issue of it right  
5 now. I just wish to bring the point up that I am  
6 afraid that we are going down the wrong road here.

7 CHAIRMAN CERQUEIRA: John, and then  
8 Nekita. John, do you want to go first.

9 MR. GRAHAM: Dr. Howe, could you just  
10 clarify in light of the 1994 rules that were  
11 established for the radiopharmaceuticals? At least  
12 the discussion that the ACMUI has had, where we  
13 generally supported broad authorizations.

14 Why did the NRC staff instruct its regions  
15 that individual licensees had to accept a condition  
16 that it was only to be used specifically as it was  
17 approved by the FDA? I mean, it is like what went out  
18 to the field was different than everything that got  
19 talked about at a very high broad policy level.

20 DR. HOWE: I think there were issues  
21 associated with devices that we had already addressed  
22 with radioactive drugs, but they had not been  
23 addressed with the medical devices yet, and so the  
24 staff wanted to develop a policy and come up with the  
25 best possible policy.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1           And in the meantime not be seen as a  
2           hinderance in letting these devices be used at limited  
3           specific licensee sites.

4           More of our limited specific licensees  
5           were coming in and were requesting authorization to  
6           use the devices that had just been approved, and were  
7           mimicking the indications for use on the FDA  
8           approvals.

9           So there was a good match-up between  
10          limiting to the FDA approval and what the licensees  
11          were asking for, and that gave us time to discuss and  
12          air a lot of the policy issues that you will be seeing  
13          as we go to a broader authorization.

14          So I think it was done that way to  
15          expedite getting it out while larger policy issues  
16          could be discussed and resolved, and currently we are  
17          in the process of resolving those and anticipate  
18          coming out with a much broader authorization.

19                 CHAIRMAN CERQUEIRA: Okay. Nekita and  
20                 then Dr. Brinker.

21                 MS. HOBSON: Well, just building on what  
22                 Lou said, it seems to me that going back to number one  
23                 in the medical use policy statement, where you state  
24                 the NRC's mission is to regulate radionuclides in  
25                 medicine for the safety of workers and the general

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 public, if you just inserted the work patients in  
2 there, then you could do away with number three  
3 totally.

4 Because I agree that the way that it is  
5 worded it is really going to get the NRC in really  
6 pretty deeply into a particular case, and trying to  
7 decide all the things that Lou said.

8 You know, was it the right amount and was  
9 it the right isotope, and was it delivered properly.  
10 And unless it affects safety, why do it.

11 DR. HOWE: Well, I know that the ACMUI and  
12 the NRC just revised the medical policy statement to  
13 be these four items, and so I think that is an issue  
14 that you may want to bring up for further  
15 consideration. But you have just gone through rule  
16 making to get to these.

17 CHAIRMAN CERQUEIRA: Jeff, and Dr.  
18 Brinker.

19 DR. BRINKER: First, I would like to thank  
20 the committee for allowing me to attend this meeting,  
21 and I appreciate the concerns brought up by committee  
22 members with regard to expanded use of intervascular  
23 brachytherapy.

24 I just have one question and one comment.  
25 The question is that the cardiology and their

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 colleagues in therapeutic radiology are in a bit of a  
2 paranoic state because we have heard different things  
3 from different sources pertaining to how we can treat  
4 the actual patient who shows up today or tomorrow, or  
5 yesterday, who has a recent in-stent restenosis or a  
6 longer in-stent restenosis that requires a pull back  
7 technique for certain devices.

8 And these patients are often the most  
9 refractory and the most critical to treat, and there  
10 is some hesitancy to treat them on what we would  
11 normally call a compassionate off-label basis because  
12 of concerns about our nuclear license.

13 So the first question I would have is what  
14 can we do today or tomorrow to counsel physicians  
15 involved in this every day practice; and the second  
16 question I have is once an official position is taken  
17 by the NRC, how will that be propagated down to the  
18 levels of the treating physician, since it would be  
19 wrong for industry to say it is all right, and you can  
20 do it.

21 It would be against FDA policy for  
22 advocating an off-label use. So there must be some  
23 other way of doing this in a responsible fashion.

24 DR. HOWE: With respect to compliance with  
25 FDA and off-label uses, that's going to be the

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701



1 responsibility of the licensee, and FDA, to make a  
2 determination of whether that's significant to them or  
3 not.

4 DR. BRINKER: That wasn't actually my  
5 question.

6 DR. HOWE: But I would refer to John  
7 Hickey.

8 MR. HICKEY: Yes, John Hickey. We have  
9 ways of electronically transmitting the position to  
10 our own licensing staff, and all of the agreement  
11 States who regulate most of the hospitals.

12 And then we also have a pool of about 30  
13 to 50 institutions that have expressed interest in  
14 this procedure that we would notify, and we would ask  
15 the agreement States to notify their hospitals. So it  
16 can be done very quickly.

17 DR. BRINKER: And I appreciate that, and  
18 my first question is sort of -- well, when I get back  
19 today and have a patient with unstable angina, with  
20 in-stent restenosis and a stain graph, and who has  
21 come for his third time and has no option, what do I  
22 do?

23 I mean, I know what I will do, but how  
24 will I suffer the slings and arrows for doing it?

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 MR. HICKEY: Well, clearly the use would  
2 be to ask for an amendment to your license, and that  
3 could be done very quickly on an emergency basis.

4 CHAIRMAN CERQUEIRA: Not as quickly.

5 DR. HOWE: No. No, what we have to do as  
6 we are developing a larger policy issue, if we have  
7 individual patient concern issues, we handle those  
8 very quickly. I defer to John Hickey again for any  
9 comments.

10 MR. HICKEY: Well, we have emergency  
11 authorization procedures that go into other issues,  
12 and we sometimes issue authorizations within minutes  
13 of getting a request if there is a patient that needs  
14 to be treated.

15 CHAIRMAN CERQUEIRA: We have Mr. Heaton,  
16 who is an FDA representative, and I would like to get  
17 his comments on some of these issues that have been  
18 discussed, in terms of when a device has been  
19 approved, and if Dr. Brinker decides this afternoon  
20 that he is going to use it independent of the  
21 radiation safety issues, what is the FDA's position?

22 MR. HEATON: There is really two different  
23 issues in here as far as I am concerned. One is the  
24 brachytherapy, does interventional brachytherapy, and  
25 prostate cancer is going through the 510(k) route, and

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1       that was what I was talking about mostly here in the  
2       presentation.

3               I don't have any real comment on that. If  
4       you are going through the intervascular route, FDA's  
5       position is that it simply states in our law that the  
6       FDA does not regulate the practice of medicine.

7               If you want to use something off-label,  
8       that's a practitioner's preoperative to decide how  
9       they will use an FDA's approved device. For FDA to  
10      become more involved in the whole issue is if you  
11      decide to do our own study to see if you can start  
12      doing it off-label, and then report that.

13              Then you need both the IRB, as well as an  
14      IDE, to start doing it. But the individual patient's  
15      treatment is up to the practitioner.

16              CHAIRMAN CERQUEIRA: So we have from again  
17      the NRC that they want to stay out of the practice of  
18      medicine. The FDA, also within certain limits, feels  
19      the same way. So I think we are getting some uniform  
20      consensus. John, and then David.

21              MR. GRAHAM: Well, I guess in summary,  
22      because I think part of it is this timing issue, and  
23      part of it is in the tradition of the NRC, you send  
24      out a fairly prescriptive limited interpretation while  
25      the policy was being debated.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1                   But as I understand it as a lay  
2 administrator, and not as a practitioner, that there  
3 are patients that right now create an essentially  
4 legal dilemma for practitioners because they will be  
5 in violation of the NRC restrictions on their licenses  
6 if they uses these devices beyond the FDA indication,  
7 correct?

8                   Now, I understand that you have emergency  
9 authority to send out communiques, and so I guess I  
10 would suggest that this group may want to pass as a  
11 motion that ACMUI recommends immediate NRC acclamation  
12 of the concept of broad authorization for  
13 brachytherapy licensing, rather than restricting the  
14 licensing authorization to strictly follow the FDA  
15 approved indications for use.

16                  MR. AYRES: Could I make a correction to  
17 one thing, Donna-Beth, and I think it is important to  
18 the example. We didn't stick completely with the FDA  
19 requirements. We didn't include the word native, and  
20 so the example that was given about the staff and the  
21 stain graph would not be in violation of our current  
22 authorizations.

23                  DR. HOWE: Okay.

24                  DR. DIAMOND: It is very difficult, Bob,  
25 trying to guess what the intent was in that type of

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 language. I myself now that you said it have treated  
2 a number of people with STP graphs, because that is my  
3 interpretation. But a lot of other folks won't do it  
4 because of that paranoia.

5 But to answer the question of what can we  
6 do to help our patients in the immediate future, I  
7 would support that the committee at this time address  
8 a resolution somewhat along the lines of what John has  
9 just put forward, and that we ask that the NRC staff  
10 promulgate this in a very effective fashion to all of  
11 its stakeholders, particularly the agreement States.

12 And that individuals or institutions that  
13 have broad scope licenses, such as Hopkins or my  
14 institution, that would allow us to immediately start  
15 doing these procedures for institutions that have a  
16 limited scope license.

17 They could go and modify their licenses to  
18 reflect this new language as well. So I think what  
19 you could see is if we move today a large number of  
20 centers very, very quickly and be able to provide this  
21 to their patients.

22 CHAIRMAN CERQUEIRA: So I interpret that  
23 as a second to John's motion; is that correct?

24 DR. DIAMOND: In a very loquacious way,  
25 yes.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 DR. HOWE: I am just slightly confused,  
2 because your broad scope licensure already has a very  
3 broad authorization, and they are not limited to --

4 DR. DIAMOND: Paranoia will destroy you  
5 though as they say, and we get very concerned, or the  
6 administration and the radiation safety office gets  
7 very, very concerned about going out there -- the  
8 practices get very concerned about medical liability  
9 issues.

10 So this type of affirmation would make all  
11 of us feel a lot more comfortable; and then  
12 secondarily, it will allow the limited scope holders  
13 to go and modify any licenses that they need to  
14 modify.

15 CHAIRMAN CERQUEIRA: A comment from John.

16 MR. GRAHAM: Let me just state what I am  
17 recommending as the motion that I think that Dr.  
18 Diamond is proposing to second, because it is to try  
19 and give that type of clarification of broad licensees  
20 as well.

21 It's that the ACMUI recommends immediate  
22 NRC affirmation of the concept of broad authorization  
23 for brachytherapy licensing, rather than restricting  
24 the licensing authorization to strictly follow the FDA  
25 approved indications for us.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1           So by making that statement, you are  
2           giving a level of guidance to the broad licensees as  
3           well of where the boundaries are being set. And all  
4           I think I am doing is trying to facilitate what you  
5           have been discussing is where the staff has landed on  
6           their recommended interpretation of this policy  
7           anyway.

8           CHAIRMAN CERQUEIRA: I think again that is  
9           a very good restatement. One more comment from Jeff,  
10          and then I think we should try to wrap it up.

11          MR. WILLIAMSON: Just to support this sort  
12          of issue of the sort of paranoia, I read from  
13          something from the ASTRO list server received on April  
14          17th.

15          And I quote, "A representative from the  
16          Nuclear Regulatory Commission has indicated that any  
17          off-label use of intervascular brachytherapy other  
18          than FDA approved indication will be considered a mis-  
19          administration."

20          So I think that is what you have to  
21          counter.

22          CHAIRMAN CERQUEIRA: So I think you have  
23          gotten a sense from this committee that everybody is  
24          -- and even the FDA didn't feel that they are going to  
25          regulate it that tightly.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1           So we have a motion on the floor that has  
2       been seconded, and we have had discussion. If there  
3       is no further discussion, I call for a vote on the  
4       committee. All those in favor of the proposal?

5           (A show of hands.)

6           CHAIRMAN CERQUEIRA:     Nine in favor.  
7       Opposed? Abstentions? So, one abstention from Ruth,  
8       representing the agreement States.

9           I think you have gotten a fairly  
10      consistent feedback from all of the people here, and  
11      again it is in line with the Part 35 revision, which  
12      is to stay out of the practice of medicine, and really  
13      deal with radiation safety.

14          All right. I think we should break for  
15      lunch. We will make every effort to start at one  
16      o'clock.

17          (Whereupon, the advisory committee was  
18      recessed at 12:09 p.m.)

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701



1  
2  
3  
4  
5  
6  
7  
8  
9

A-F-T-E-R-N-O-O-N S-E-S-S-I-O-N

(1:00 p.m.)

CHAIRMAN CERQUEIRA: All right. I would like to welcome everybody back for the afternoon session, and a couple of people said they have like six o'clock flights, and so later on in the agenda there is some items that will not be discussed as long, and we may actually get done a little bit earlier, which would be very useful.

The first presentation after the lunch is going to be Physical Presence Issue for New Brachytherapy Procedures, Presence of medical Physicist, Cardiologist, et cetera, and Fritz Sturz will be presenting that.

MR. STURZ: I think as you heard in your last meeting back in November, and in previous sessions, the new brachytherapy treatment systems have been approved by FDA in November, and I won't go into that.

But what we want to talk about today is to identify the medical personnel to be present during intervascular brachytherapy treatments for in-stent restenosis, and I want to focus on what skills need to come into play here for the radiation safety of patients and workers.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

(202) 234-4433

(202) 234-4433

1           It is not necessarily who needs to be  
2           here, but what skills need to be brought to the plate.  
3           On this slide, we just try to break down some of the  
4           procedures for intervascular brachytherapy and who  
5           brings some of the critical skills and --

6           DR. NAG:   Excuse me, but before you go  
7           forward, how did you make these determinations?  How  
8           were these determinations done?

9           MR. STURZ:  This is just kind of looking  
10          to see what the skills were and who might be the  
11          principal parties.

12          DR. NAG:   Is that from your or from a  
13          society, or is that from a governing body?

14          MR. STURZ:  This is just from what we have  
15          as far as the information from FDA approval.  It is  
16          just up there for discussion, and it is not  
17          necessarily --

18          CHAIRMAN CERQUEIRA:  So I guess this is an  
19          NRC attempt to identifying who is doing what.

20          DR. NAG:   But this is not from any body or  
21          professional society?

22          MR. STURZ:  No.

23          DR. NAG:   There are publications on this  
24          already.  There are official publications that are  
25          printed.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 CHAIRMAN CERQUEIRA: There are various  
2 professional medical societies that are working  
3 together to try and come up with some definitions of  
4 who is doing what.

5 MR. STURZ: This is just to show that  
6 different people are involved in different parts of  
7 the process. It is not hard and fast there. This is  
8 just an example.

9 In your handout that was provided in the  
10 previous meeting, it showed some background on how we  
11 got to where New Part 35 requirements to have the  
12 physical presence for high dose rate after loading  
13 device, both authorized user and the authorized  
14 medical physicist being present during initiation, and  
15 during and throughout the treatment.

16 So this is what we want to focus on, on  
17 who needs to be present during intervascular  
18 brachytherapy, both during initiation and throughout  
19 the whole treatment.

20 So right now our licensing guidance to our  
21 region says that the authorized user and the medical  
22 physicist, or RSO, needs to be present and consistent  
23 with the FDA guidance, and also the interventional  
24 cardiologist.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 DR. DIAMOND: Excuse me, sir, but in the  
2 present -- if we are discussing SFAs, I would assume  
3 that an interventional radiologist, if he or she does  
4 that, would be appropriate as well?

5 In other words, when you say that the  
6 physical treatment of the team, this is for  
7 intracoronary radiation. But if you are talking about  
8 the superficial feral artery system, in many cases it  
9 is the interventional radiologist doing it.

10 And it just depends on the training and  
11 the specifics of that institution, and whether the  
12 radiologist or the cardiologist is doing it.

13 MR. STURZ: Well, we understand that a  
14 cardiologist is going to be doing the procedure, and  
15 it gets down to the radiation safety, and it is the  
16 authorized user and medical physicist until such time  
17 as the cardiologist becomes an authorized user.

18 DR. DIAMOND: I think you missed the  
19 point. I guess what I am saying is that what you have  
20 is correct for the coronary circulation.

21 MR. STURZ: Yes.

22 DR. DIAMOND: But we also are now starting  
23 to treat the extremities, such as the feral artery,  
24 which is in your thigh essentially, and in that case  
25 depending on where you are, in some institutions it is

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 an interventional radiologist and not a cardiologist  
2 that does the procedure, although some interventional  
3 cardiologists of course do peripheral vascular work as  
4 well.

5 MR. STURZ: It would have to change, but  
6 I guess the issue is that who needs to be there for  
7 radiation safety.

8 CHAIRMAN CERQUEIRA: And I guess the other  
9 question that I have is it medical physicist or RSO,  
10 or do you always need to have a medical physicist  
11 present, and he could or may not be the RSO.

12 MR. STURZ: That's kind of what we want to  
13 discuss here today.

14 CHAIRMAN CERQUEIRA: Okay. So a lot of  
15 these things are going to be discussed rather than  
16 just being --

17 MR. STURZ: Yes.

18 CHAIRMAN CERQUEIRA: Okay.

19 MR. STURZ: So just to let you know that  
20 in the past couple of weeks we have gotten two letters  
21 in from two different medical societies, and that they  
22 endorse the approach, the team approach, that the NRC  
23 and the FDA has taken, and that it should be  
24 continued.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1           The American College of Radiology and the  
2           Society of Cardiac Radiology and Interventions also  
3           committed to developing a curriculum and training  
4           standards, which include clinical experience and  
5           didactic, and they said that would take about 18  
6           months for them to prepare and submit to the NRC for  
7           our consideration.

8           CHAIRMAN CERQUEIRA: Just a typographical  
9           error. That should be the American College of  
10          Cardiology on top, and not radiology. That would be  
11          a first, the two of them working together.

12          DR. NAG: When you have a society  
13          recommendation already there, there is the previous  
14          publication that is already there on intervascular  
15          radiation and personnel issues that have been  
16          published, and that were sent to the NRC about a year-  
17          and-a-half ago in one of the earlier meetings.  
18          So I can give you a copy of that.

19          MR. STURZ: So some of the points that we  
20          just threw out for discussion and don't limit yourself  
21          to these questions, but obviously it is important to  
22          have a trained physician available at all times to  
23          respond to emergency situations that require source  
24          removal.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1           And I guess the question before us is does  
2           the inherent risk of high dose rate intravascular  
3           brachytherapy, whether it is manual or remote, justify  
4           both the authorized user and the authorized medical  
5           physicist to be physically present throughout the  
6           treatment.

7           Or can it be somebody who has been trained  
8           in the operation, but is under the supervision of the  
9           authorized user be present. If not both of them, then  
10          could it be either of the authorized users, or the  
11          authorized medical physicist.

12          Or can we leave the decision up to who  
13          should be physically present be the responsible  
14          authorized user; or is there something different that  
15          we can use besides physical presence or on call.  
16          These are the kinds of things that we would like to  
17          have you discuss and get some recommendations.

18          CHAIRMAN CERQUEIRA: Well, maybe we could  
19          just go through the questions, and there is five  
20          questions up there, and maybe we could try to address  
21          each one individually.

22          And I guess the answer to number one, I  
23          think you needed a trained physician.

24          DR. ALAZRAKI: Are we talking about under  
25          the current rules or the new rules?

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701



1 MR. STURZ: Well, right now we are under  
2 the current rules, but six months from now we could be  
3 under the new rules, and so we would like to hear  
4 both.

5 DR. NAG: And are we only talking about  
6 intervascular brachytherapy high dose rate, or are we  
7 talking about all intervascular, or are we talking  
8 about all high dose rates? They have different  
9 implications.

10 MR. STURZ: I think we are limiting it to  
11 high dose rate IVB.

12 DR. NAG: So intervascular, high dose rate  
13 intervascular only?

14 MR. STURZ: Yes.

15 DR. NAG: Okay.

16 MR. WILLIAMSON: And what is your  
17 definition of high dose rate?

18 MR. STURZ: It is in our guidance.

19 MR. AYRES: It is in your rules that you  
20 have in front of you.

21 CHAIRMAN CERQUEIRA: What does the ICRU  
22 stand for, Dr. Nag?

23 DR. NAG: The International Commission of  
24 Radiation Units.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 MR. WILLIAMSON: Radiological Units and  
2 Measurements.

3 CHAIRMAN CERQUEIRA: Well, for point one,  
4 I think we would all agree that you need to have a  
5 physician present for any sort of intervascular  
6 procedure, because somebody has to introduce the  
7 catheter.

8 Does anybody feel comfortable that once  
9 the catheter is in there that a physician is no longer  
10 required?

11 MR. WILLIAMSON: I think the question is  
12 more focused than you are making it. Does a physician  
13 need to be there to implement the emergency response  
14 if something happens, and not take care of the  
15 patient.

16 CHAIRMAN CERQUEIRA: Okay. It does say  
17 source removal.

18 MR. WILLIAMSON: Yes, but they are not  
19 concerned about the quality of practice in  
20 interventional cardiology per se, but does somebody  
21 with specific training, whose job it is to respond to  
22 -- well, for example, the equivalent of a source  
23 detachment in HDR.

1 CHAIRMAN CERQUEIRA: Well, I guess as long  
2 as the catheter is still in the patient, you need a  
3 physician there.

4 MR. WILLIAMSON: I think that is correct,  
5 since basically in the procedure the physicist is sort  
6 of standing aside that is going to be the cardiologist  
7 or radiation oncologist, and there will be some  
8 physician that is manipulating the catheter, who will  
9 probably grab a hold of the thing and naturally be the  
10 first to respond.

11 And it is probably logical to saddle that  
12 person, or burden that person with the responsibility  
13 for having the additional training.

14 DR. NAG: I think what you need in that  
15 moment of emergency is somebody who in a split second  
16 can think in both directions, and think as a  
17 physician, and therefore be comfortable removing the  
18 catheter or removing the source wire.

19 And also in that split second, also has  
20 the radiation background to think of all the radiation  
21 safety aspects. So you need or there definitely has  
22 to be a physician, and it also needs to be a physician  
23 with sufficient training in radiation safety to know  
24 all of the radiation safety issues.

25 CHAIRMAN CERQUEIRA: Jeffrey.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1                   MR. WILLIAMSON: Well, just as a sort of  
2 general comment, I think maybe there are two sort of  
3 axes to examine here in deciding what physical  
4 presence means.

5                   I think one axis is time. If something  
6 does happen, how quickly does someone need to respond  
7 in order to correct it to avoid a medical event or  
8 misadministration. I think that would be the issue.

9                   And I think there would be a big  
10 difference between the best cardias system which might  
11 have a 15 or 20 minute treatment time, and the current  
12 Novoste system, which would have a very short time.

13                  And a radioactive stent for example, if it  
14 were deployed would obviously be a different time  
15 scale altogether, and you could imagine different  
16 kinds of products in the future.

17                  So one issue that relates to physical  
18 proximity is how long do you have to respond. So a  
19 three minute response time does not mean that the  
20 person needs to be standing in the room. A 15 second  
21 response time means that they do. The second axis, I  
22 think, of the --

23                  CHAIRMAN CERQUEIRA: Well, let's talk  
24 about that first one, because obviously if something  
25 happens, you need to take immediate action, and we

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 have agreed that a physician needs to be there who is  
2 manipulating the catheter, whether it is a  
3 cardiologist, an interventional radiologist, or --

4 MR. WILLIAMSON: Could I finish? It  
5 really is important for me to finish my comment,  
6 because it impacts --

7 CHAIRMAN CERQUEIRA: Well, you were going  
8 on to the second one.

9 MR. WILLIAMSON: Yes, but they are  
10 related.

11 CHAIRMAN CERQUEIRA: Okay.

12 MR. WILLIAMSON: The second axis is the  
13 technical complexity of the device. Now, some  
14 devices, like the typical high dose rate and pulse  
15 dose rate remote after loading systems are fairly  
16 complicated systems, and it takes a significant level  
17 of technical skill sometimes to recognize that an  
18 emergency has occurred, and to sort of be able to  
19 respond to contain it.

20 And I think that is one of the major  
21 reasons for requiring a physicist to be there, for  
22 example. Now, I think these two axes could be  
23 different in intravascular brachytherapy than they are  
24 for typical high dose rates.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1           So one could make the case with some of  
2       these methods that maybe the manipulation of the  
3       device is sufficiently simple that you don't have to  
4       have a physicist on the front line to be able to sort  
5       of maybe pull the catheter out.

6           It is not rocket science to figure out  
7       that it is in the wrong place or that it has been too  
8       long. So I guess they are related in that sense. So  
9       it is technical complexity, which is the ability to  
10      recognize something has gone wrong, and then response  
11      time if something has happened.

12           CHAIRMAN CERQUEIRA: Richard.

13           DR. VETTER: You are using the word  
14      available in here, and in the background material that  
15      you gave us, you used two different terms, physically  
16      present and immediately available.

17           So that this is different, number one,  
18      than either of those. And physically present means  
19      within hearing distance, the distance of the normal  
20      voice; whereas, immediately available means available  
21      on an on-call basis, such as by telephone.

22           MR. STURZ: Would there be different  
23      situations where being available on call would be more  
24      appropriate than physical presence? I think that  
25      these are kind of some of the issues that maybe there

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 is a need for somebody that may not be needed right  
2 there in the treatment room, but could respond within  
3 a short amount of time.

4 DR. VETTER: Well, for IVB brachytherapy,  
5 you need an oncologist just to be there. I mean,  
6 under the current rules; or a cardiologist, one or the  
7 other anyway. You need a physician there implementing  
8 the technique. So it is almost a moot point. There  
9 has to be someone there.

10 CHAIRMAN CERQUEIRA: Dr. Brinker, you had  
11 a comment?

12 DR. BRINKER: I think I was going to  
13 pretty much echo what you just said. I think nobody  
14 could argue with point number one that it is important  
15 for a properly trained physician to be available at  
16 all times.

17 And I was going to bring up the point that  
18 there are two problems that can occur with this form  
19 of therapy. The most common problem that would  
20 require an immediate response is acute ischemia due to  
21 the physical presence of the delivery system.

22 And that is best handled by the  
23 cardiologist changing that physical presence in some  
24 way. The other issue is a potential now deployment if  
25 you will of the source train.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1           And that the way that the guidelines are  
2 written now, it is the responsibility of the radiation  
3 oncologist. I think as things evolve that I would  
4 strongly suggest that there is some flexibility built  
5 into the approach that the NRC takes to allow sites to  
6 quality their properly trained physicians in an  
7 appropriate fashion, so that all three members of this  
8 very important team need not necessarily be physically  
9 throughout the entire procedure, which is what I would  
10 suggest.

11           But I think if you want to just look at  
12 Item number one, that's fine. The issue is properly  
13 trained I think needs a little bit of flexibility.  
14 But you don't have to work on that right now to accept  
15 that point.

16           CHAIRMAN CERQUEIRA: Any other comments?  
17 Dr. Nag.

18           DR. NAG: I think since we are starting to  
19 make rules, I would like the rules to be done in such  
20 a way that they will be applicable not only to the  
21 methods that we are using today, but also the methods  
22 that we will be using tomorrow.

23           For example, today, yes, you are using a  
24 hand held uranium wire or the strontium. But tomorrow  
25 we are going to be using HDR, or whatever. I think we

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701



1       should make the rule broad enough so that tomorrow we  
2       don't have to reissue our rule again.

3               So my comment that I am going to make is  
4       with that in mind. That, one, that the personnel who  
5       are there would depend on which exact equipment is  
6       being used, because if it is a remote HDR applicator,  
7       that is quite different from, let's say, if you have  
8       something with strontium.

9               I think that is one important thing that  
10       you should keep in mind when you are making these  
11       rules.

12               CHAIRMAN CERQUEIRA: So how do we go and  
13       write rules that can guide us many years into the  
14       future when we don't know again what some of these may  
15       be?

16               In other words, we spent a lot of time  
17       earlier today trying to avoid nitpickingness in rules  
18       and regulations without -- in other words, that you  
19       don't identify specific systems and the details of  
20       particular techniques.

21               So how can we accomplish your goal without  
22       being overly prescriptive?

23               DR. NAG: Well, I think that is a good  
24       question. I would suggest that these treatments are

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1       only being done over a period of 3 to 15 or 20  
2       minutes.

3               And therefore if even there is a high dose  
4       rate after loader, you would be 2 or 3 minutes, and if  
5       it needed a manual high dose rate after loader, it  
6       would be about 10 or 12, or 15 minutes.  
7       So all of them are within that time frame, no matter  
8       which of the equipment we are using.

9               Some may be a little shorter, but some  
10       will be a little longer, but not much more than 15 or  
11       20 minutes. So the personnel that we have I think we  
12       can do keeping that in mind; as opposed to something  
13       like stents, where it is in there permanently.

14              And so I am talking about the removal,  
15       only the removal system, and we have one set of rules,  
16       and for the permanently placed system, like the stent,  
17       we have a separate set of rules.

18              MR. STURZ: But again stents is not really  
19       the primary technique for discussion today.

20              DR. NAG: Right.

21              MR. STURZ: So again, I don't want to get  
22       too prescriptive on the details.

23              CHAIRMAN CERQUEIRA: Yes, this was an  
24       issue that over the last two years that we have had  
25       multiple discussions, and since we didn't have an

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 approved system when we were trying to draft Part 35  
2 revisions, we put this into the emerging technology  
3 category, the 35.1000.

4 We are getting to the point now where  
5 there are some devices that are approved, and we need  
6 to at least start to think about it, and I think that  
7 is what this discussion is going to be on. Naomi.

8 DR. ALAZRAKI: I think this is entirely  
9 too prescriptive a discussion, and we should be  
10 thinking more in generalities that are more  
11 appropriate I think for the NRC to be talking about  
12 for protection of personnel and of the public.

13 You have defined a team, and I don't think  
14 we should be saying what or how the practice of  
15 medicine should go on for this individual patient.

16 You have defined a team, and perhaps you  
17 want to state some of the radiation safety  
18 requirements in the sense that the team will ensure  
19 that there will be minimal or no -- minimal to no  
20 possibility of any radioactivity leaving the intended  
21 location.

22 And that if that should occur, the team  
23 will be capable of responding in the appropriate  
24 timely fashion to correct the problem and so forth,  
25 you know.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 But I don't think we should be talking  
2 about exactly prescriptively for each device how  
3 things are going to work.

4 CHAIRMAN CERQUEIRA: Jeffrey.

5 MR. WILLIAMSON: I was going to suggest a  
6 slightly different tactic, and it is different than  
7 what Naomi suggested, but I would say that we think  
8 what is about in 35.400 and 600, and think whether the  
9 device -- how similar or different the device is from  
10 there.

11 Now, for example, a full-blown single  
12 stepping source remote after loading device, there is  
13 a fairly carefully worked out scenario of who has to  
14 be there.

15 So I think for an intervascular treatment  
16 outside of the cardiac tree, where the patient would  
17 be treated nowadays with a conventional remote after  
18 loader, it seems to me that there is no reason  
19 whatsoever to have sort of special regulations.

20 It is already covered and the requirement  
21 is that a medical physicist be there all the time, and  
22 authorized user there to start the treatment, and a  
23 properly trained physician, and not necessarily the  
24 authorized user, be there to implement certain parts

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 of the emergency response procedure if it is necessary  
2 and leave it at that.

3 And I would say that some device that has  
4 a technical complexity comparable to the single  
5 stepping source remote after loader may be the same  
6 approach, and might want to be used.

7 Now, manual brachytherapy on the other  
8 hand, no matter how high a dose rate it is, does not  
9 require continual physical presence of the authorized  
10 user or the physicist.

11 It requires a physicist appropriately to  
12 be involved in calibration, and checking the  
13 calculation. It involves the authorized user to be  
14 there at the initiation of therapy, and I think the  
15 requirements should be that somebody -- and I think a  
16 physician from the sense of the discussion here, and  
17 who is properly trained to respond to an emergency  
18 condition be there if it is necessary to pull the  
19 source train out.

20 That certain manual would cover the best  
21 system that is now available, and we could argue or  
22 discuss where the Novoste system or sort of mini-hand  
23 held remote after loaders like that fall.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1           My sense would be that maybe it could be  
2           treated as an almost manual brachytherapy device. So  
3           that is another way to think about it.

4           DR. DIAMOND: Do you think then from our  
5           discussion that it would seem that you are fairly  
6           satisfied that there are current regulations on the  
7           books that would go and address the vast majority of  
8           these techniques; is that the sense that you are  
9           conveying?

10           In other words, manually loaded, or a  
11           remote after load system, there appears to be -- there  
12           are regulations that would cover these procedures to  
13           your satisfaction?

14           MR. WILLIAMSON: I think so, and I think  
15           they --

16           DR. DIAMOND: Because I think they do.

17           MR. WILLIAMSON: I think they allow a lot  
18           of flexibility. They are carefully thought out,  
19           taking into account both the sort of complexity axis  
20           and response time axis to reflect the standards of the  
21           community.

22           I don't see why a 20 minute treatment in  
23           the case of malignancy is any less dangerous or more  
24           dangerous than a 20 minute treatment in the cardiac  
25           tree for a comparable dose.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 DR. DIAMOND: I agree with you. I think  
2 that the discussion is almost moot because to me high  
3 dose brachytherapy is high dose brachytherapy, and the  
4 distinction is manual versus remote.

5 MR. WILLIAMSON: I think so.

6 DR. DIAMOND: And the regulations are  
7 there, and they work, and people are protected.

8 CHAIRMAN CERQUEIRA: I guess the issue  
9 with some of these hand held manual type devices is  
10 that they are emerging technology in the application,  
11 and so the discussions that we have had in the past  
12 was that they would probably need to be relooked at in  
13 the future when they were approved and considerations  
14 being made. And which I think is still under  
15 discussion.

16 DR. NAG: Manuel, one thing.

17 CHAIRMAN CERQUEIRA: Yes.

18 DR. NAG: I think here again as an  
19 emerging technology, we have to differentiate the two  
20 issues. One is the medical necessity and the medical  
21 applicability, and the radiation safety.

22 The radiation safety issue, even though  
23 this is an emerging technology, instead of using it in  
24 the esophagus, you are using it in the coronary  
25 vessel.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1           The medical applicability and the medical  
2           indications are different, but the radiation safety  
3           indications are exactly the same as whether you are  
4           using the high dose rate in the coronary vessel, or in  
5           the esophagus, or in the lung.

6           And I agree with Jeff that the regulations  
7           offer the use of any high dose radiotherapy is already  
8           worked out in other organs, and in terms of the  
9           radiation safety issue, it is no different doing it in  
10          the heart.

11          So, therefore, instead of trying to make  
12          a new set of regulations, try to implement the same  
13          set of regulations and it is much easier for  
14          everybody.

15          CHAIRMAN CERQUEIRA: I think those are  
16          good points. We have had discussions here in the past  
17          from the cardiology community. We had Dr. Razner here  
18          last time, and we have had Dr. Warren Laskey in the  
19          future, and there was some discussion whether these  
20          things would be done emergently.

21          Well, you didn't have all the  
22          appropriatial elective time to do all these  
23          procedures, and there was a time element on things  
24          that you needed to initiate for treatment in a timely  
25          fashion.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701



1           And there were issues related to how many  
2 people did you need there, and what would be the  
3 training requirements. And there was some input from  
4 the cardiology community that there would be  
5 considerable delays introduced related to patient  
6 safety by having a whole team approach.

7           DR. DIAMOND:     So, for example, we  
8 discussed it with Dr. Rasner last time that the  
9 outcome of the patient is our primary concern.  
10 However, if you follow the same logic that time is  
11 always of the primary importance, then by extension,  
12 one could do these procedures without any oversight  
13 whatsoever.

14           And then in that regard, then you are  
15 really starting to move in an area where there may not  
16 be an appropriate degree of oversight in my opinion.

17           For example, let's say that at two o'clock  
18 in the morning a person is having an acute MI, and  
19 someone wants to use vascular brachytherapy. I  
20 personally think it would be extremely dangerous to  
21 the public safety to have these procedures being done  
22 by a cardiologist and a cardiologist alone in the  
23 middle of the night.

24           I just can't even begin to fathom that  
25 type of thing. So I fully understand that particular

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 point of urgency, but we can't go and sacrifice that  
2 time urgency for the primary case of safety and  
3 oversight.

4 CHAIRMAN CERQUEIRA: Well, I don't think  
5 that was the point, but Dr. Brinker, you had a  
6 comment?

7 DR. BRINKER: Thanks. This is obviously  
8 a very complex issue and technology is evolving such  
9 that many of the classical relative roles will change.

10 And what I would propose is to think about  
11 flexibility now so that when one can adjust a bit to  
12 the future. But I would like Dave to take away the  
13 idea that cardiologists would consider doing this all  
14 by himself in the middle of the night for an  
15 emergency, because I don't think that is appropriate.

16 On the other hand, I can tell you a true  
17 problem as a practicing cardiologist with an approved  
18 device, and that is that many, many institutions do  
19 not have the radiation oncology manpower to give not  
20 24-7, but five day a week, 8 hour coverage.

21 And I have the utmost respect for my own  
22 radiation oncologist at Hopkins, who are underpowered  
23 right now, and who are wonderful people, and who have  
24 worked diligently with us, the cardiologists, in doing  
25 the clinical trials of these devices.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1           But right now they can only give us a  
2 half-a-day twice a week for radiation oncology  
3 coverage, and they are going to work very hard to  
4 improve that.

5           But this is not unique to Hopkins. It is  
6 not an isolated situation. It is something that I  
7 hear a lot, and what I would like to at least have  
8 people thinking about is that there are many ways that  
9 one could approach this.

10          But the way that the Europeans seem to  
11 have taken is to maintain the concept of the team  
12 approach, but have taken the position in many places  
13 in Europe that two members of the team are adequate,  
14 with the third member being available, but not  
15 physically present necessarily.

16          At least the concept of flexibility, and  
17 that is, at any one center, if all three members of  
18 the team agree that two members of the team are  
19 properly equipped to do these procedures, being  
20 physically present, and the other one being remotely  
21 present -- not at home in bed, but in another area of  
22 the hospital perhaps -- that that may be acceptable.

23          I don't think that we should reject it out  
24 of hand, and the more flexibility that we build into

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 the system, I think the better it is going to be for  
2 the patients, which is really the primary issue.

3 And I will give you another example. Two  
4 weeks ago, I had a patient admitted with unstable  
5 angina on Saturday. He had in-stent restenosis and we  
6 knew that. This is his third recurrence.

7 And I get back up only on Tuesdays and  
8 Fridays, a half-a-day each. And by Monday, he was  
9 having ongoing rest pain, and I had to take him to the  
10 lab, and I just opened up his artery a little bit with  
11 a balloon, and then brought him back the next day  
12 totally off-label compassionately, and finished the  
13 angioplasty, and then on that Tuesday did radiation  
14 therapy with the full team being present.

15 Now, this is not shown to be an effective  
16 methodology, but I felt that I had no choice for that  
17 patient, and I think that around the country that  
18 there are a million angioplastys a year, and 80 plus  
19 percent of them get stents.

20 And in-stent restenosis makes up about 20  
21 percent of the patients we do now. We are talking  
22 about huge numbers.

23 And if you had a stent and you came in and  
24 somebody said, well, we really can't do you here until  
25 the next day or two days down the line, you will just

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 have to make do with what you have, it is an  
2 uncomfortable thing that I think is not necessitated  
3 by true safety concerns.

4 I think in the proper environment, with  
5 all three people, entities working together, these  
6 things can have a flexibility that will allow greater  
7 efficiency without any sacrifice of safety.

8 And that is at least a goal that I would  
9 like to think we could think about, in terms of  
10 flexibility.

11 CHAIRMAN CERQUEIRA: Dr. Nag.

12 DR. NAG: Yes. Dr. Brinker, you are not  
13 really opposed to having the whole team. Your concern  
14 is two things. Number One, the manpower that you feel  
15 in radiation oncology to back you up; and, number two,  
16 and it may not be you directly, but some of the other  
17 oncology community having a feeling that they may not  
18 have a radiation oncologist in a short enough time  
19 period to be there; am I right?

20 DR. BRINKER: I think that is a big issue.

21 DR. NAG: Now, I think rather than  
22 changing the requirements of placing safety in  
23 regulation, wouldn't it be better by having more  
24 manpower?

25 DR. BRINKER: Yes, of course.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 DR. NAG: And manpower is always generated  
2 when there is a need, and when the community feels  
3 that there is a need for more manpower, it generates  
4 more manpower. So I think that will resolve by itself  
5 if this interventional radiology does come in.

6 The other thing is that almost every  
7 hospital that does any kind of brachytherapy procedure  
8 requires a radiation oncologist on site who can come  
9 in within a few minutes notice.

10 Because if you have a brachytherapy  
11 patient with a brachytherapy source in them, this can  
12 dislodge at any moment, and then you do require  
13 someone to be able to physically come in and remote it  
14 usually within a few minutes to at least if not hours,  
15 but within a few minutes, and so you do have that  
16 backup emergency if you do need to do something in an  
17 emergency.

18 DR. BRINKER: Well, your points are  
19 extremely well taken, but I would just like to have a  
20 chance to address them. One is that in terms of  
21 manpower that will be there, and if you build the  
22 place, they will come.

23 I am not so sure, number one, that that is  
24 true. And we heard from the point of view of the  
25 physicist that if the restrictions prohibited all the

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1     physicists from doing all the things right now, there  
2     would be an acute manpower shortage that may take a  
3     very long time to rectify, and was not really a  
4     suitable answer to that particular problem.

5             The other part of that problem is that it  
6     may be that 2 or 3 years from now radiation therapy,  
7     at least as it is known today, will be supplanted by  
8     some other form of therapy.

9             And I would hate to think that you are  
10    going to build a whole manpower situation of radiation  
11    oncologists based on the proposition that you need to  
12    have 24 hour, 7 day a week, coverage for intervascular  
13    brachytherapy.

14            But those things aside, my primary concept  
15    is that if at specific sites where you have well  
16    trained cardiologists, and you have well trained and  
17    experienced medical physicists, and you have radiation  
18    oncologists who agree to supply that training and act  
19    as supervisory personnel, and who are not necessarily  
20    physically present, would that be okay at that site.

21            Not that it should be general wise, but if  
22    that site is where all people agree, could it be a  
23    working relationship. And that is the type of  
24    flexibility I am requiring with no sacrifice of  
25    safety.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 CHAIRMAN CERQUEIRA: let me just make one  
2 statement, too. As a practicing cardiologist, you  
3 have these needs. I have a 43 year old woman who had  
4 a vein graph that had gotten a stent, and came in with  
5 a stent restenosis, and was flown down from New  
6 Jersey.

7 And the treatment would have been to  
8 basically open up the stent and give her some  
9 radiation, but she gets in at 10 o'clock at night, and  
10 even though we have somebody there who is capable of  
11 doing it if we could not get a radiation oncologist to  
12 come in to do the procedure, and you have to do a  
13 suboptimal treatment.

14 I think the other point about the manpower  
15 -- and I agree with you that the ideal situation would  
16 be to have more people. But even if you geared up  
17 training programs, you are talking about at least a  
18 four year or longer delay for getting people out there  
19 who could provide enough radiation oncologists support  
20 to do that kind of training.

21 And I think the technology is certainly  
22 emerging and you might find at that point that you  
23 have trained people, but there is no need for it at  
24 that point. So I think these are issues that need to  
25 be addressed. David.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701



1 DR. DIAMOND: Just as an individual that  
2 does many of these cases, I think in my institution  
3 that we are probably number 5 or 6 in the country in  
4 volume now.

5 The way that I see this going is that the  
6 -- and particularly in light of the discussion that we  
7 had earlier, is that we are going to have an immediate  
8 future of a larger volume of cases, and a larger  
9 volume of complex cases.

10 We are going to be moving away from a  
11 system where a patient comes in with, let's say, in-  
12 stent restenosis of X and U, reflex of the respond,  
13 and this is how we are going to treat.

14 We are going to be seeing a lot more  
15 situations where there are going to be novel  
16 situations, and a lot more intellectual component to  
17 what we are doing.

18 Probably 2 or 3 years down the line there  
19 is going to be a tapering down of volume as things  
20 such as coded stents come in or soft x-rays. But in  
21 the immediate future, and we are talking, let's say  
22 two years, there is going to be an increase in volume  
23 and an increase in the complexity of what we are  
24 doing.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1           And, for example, in my institution many  
2 of the calls that I field relate to questions from  
3 interventional radiologists and interventional  
4 cardiologists that are just completely out in left  
5 field.

6           And again as these indications expand, it  
7 makes me very nervous about not being a part of it.  
8 I am very, very nervous about not being a part of it  
9 now.

10           Now, the other vision that I see is that  
11 this is not going to be a technique that is going to  
12 be available to every single cath lab in every single  
13 hospital across the country.

14           And just like every single hospital in  
15 this country does not do interventional cardiology  
16 work, I don't see every single institution in this  
17 country doing vascular brachytherapy work as well.

18           If you talk to some of the companies, the  
19 sense that I get from them is that they would like to  
20 go and focus this technique in the larger volume  
21 centers where they have more quality assurance and  
22 quality management oversight, because they realize  
23 that the higher volume institutions are getting better  
24 results.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1           So that is the second observation or  
2           expectation that I have. The third one that I have is  
3           that once again getting back to the time sensitivity.  
4           There has to be some minimum oversight that is always  
5           present.

6           For example, let's say a radiation  
7           oncologist were available, and a medical physicist  
8           were not available in the middle of the night. How do  
9           we proceed?

10           In other words, there are many times when  
11           a medical physicist may not be available. So to have  
12           it phrased as the way that you put it, Jeff, doesn't  
13           make a lot of sense to me. At our institution, we  
14           never ever do interventional cardiology work unless we  
15           have surgical backup, period.

16           You know, would we be doing these when  
17           there is no surgical background available. So I don't  
18           really buy some of these arguments very much. I see  
19           this technology being confined primarily to large  
20           volume centers that have busy interventional programs,  
21           and that have large numbers of medical physicists and  
22           radiation oncologists on staff.

23           I see the complexity of the cases  
24           increasing. The idea of doing this without a  
25           physicist or radiation oncologist at a center that

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 does not have surgical backup are things that quite  
2 frankly frighten me.

3 CHAIRMAN CERQUEIRA: Dr. Brinker.

4 DR. BRINKER: Again, Dave, I think your  
5 concerns are quite reasonable, but number one, I still  
6 agree with the team approach. I would never do  
7 anything without -- and again what I am asking for is  
8 a consensus at sites between radiation oncology,  
9 physics, and cardiology or radiology, whoever the  
10 third party is, to make their own plans as long as  
11 they have a plan that guarantees safety.

12 And, number two, the reality is that any  
13 hospital that does interventional cardiology will want  
14 to have the ability to treat in-stent restenosis, and  
15 here is the reason.

16 A patient comes in and had a stent 9  
17 months ago, and now comes in with unstable angina.  
18 You don't know what he has, and whether he has in-  
19 stent restenosis or a new narrowing.

20 So what do you do? You say, well, we are  
21 not one of these radiation centers that we are going  
22 to send you off somewhere else. That's not just going  
23 to happen.

24 And, number two, the question about back  
25 up surgery, I think that's true. We have backup

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 surgery for non-acute cases, or totally elective  
2 cases. We do not have backup surgery for emergency  
3 cases, even at Hopkins where we do these cases without  
4 a surgeon, or the weekends without a surgeon  
5 immediately available.

6 In fact, there are now procedures done on  
7 acute myocardia infarction and interventional procedures  
8 at hospitals that have no surgery backup whatsoever at  
9 any time.

10 And there is a push now for doing since  
11 stents pretty much obviate the need for emergency  
12 surgery, to take out that connotation from the  
13 performance of interventional techniques.

14 Now, all I am suggesting is that the  
15 necessity for three man team to do this procedure for  
16 most situations is I think an over-commitment of  
17 resources, at least at times when some resources are  
18 scarce.

19 And all I would suggest is that there be  
20 some mechanism, some opportunity to creatively think  
21 about mechanisms to ease this problem, and to allow if  
22 the three specialties would agree, and only if they  
23 would agree at least, to have some leeway in the  
24 regulatory process.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1           And to have them push the envelope if you  
2 will, in terms of -- or being creative in the way they  
3 approach a problem, as long as the safety remains the  
4 utmost criteria in those decisions. But it would be  
5 a three person decision.

6           CHAIRMAN CERQUEIRA: Okay. Let's try to  
7 get -- some of you have been silent, and so let's  
8 start at this end and we will sort of go around. We  
9 have heard from the radiation oncologists, the medical  
10 physicists, and the cardiologists.

11           But, Dick, at the Mayo Clinic, where I  
12 think you are doing a lot of these procedures, but  
13 what do you feel is the -- and keeping the issue of  
14 patient and staff safety in mind, and these issues  
15 that have been brought up, what do you think would be  
16 the appropriate --

17           DR. VETTER: With the current state of  
18 knowledge, I think it is appropriate to continue the  
19 team approach. I don't personally have a problem with  
20 exploring the relationship between cardiology and  
21 radiation oncology, and who does what in the future.

22           But the technology is rather new, and I  
23 think for now the team approach is the appropriate  
24 one. That has worked well at the Mayo Clinic. Again,

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 it does become a staffing issue, and it is difficult  
2 sometimes for radiation oncology to break free.

3 But they are getting better at that, and  
4 they are anticipating these a little better, and I  
5 think they all feel that at this point in time the  
6 team approach is best.

7 CHAIRMAN CERQUEIRA: I think people have  
8 mentioned the team approach, and I think one of the  
9 slides that you showed -- and I guess it was the ACCC  
10 and not the ACR that was proposing the development of  
11 training guidelines, or looking at some of these other  
12 possibilities. That would be somewhat appropriate.

13 MR. GRAHAM: I have one question for  
14 clarification, because I read the ACC letter, and in  
15 particular the affirmation of the team. But I am a  
16 bit confused now. I am hearing the endorsement of the  
17 team approach, where I think people are saying it in  
18 a definition that it is a radiation oncologist or an  
19 authorized user, along with an AMP, along with whoever  
20 the interventional physician is.

21 But I am also hearing the potential that  
22 a team is being defined as two out of the three. Is  
23 that accurate? And I just want to make sure that I am  
24 understanding that when they say that there are  
25 affirming a team, are we saying a team that is all

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 three of those as it has been described to this group,  
2 or is it any two of the three, or is that what we are  
3 debating right now?

4 MR. WILLIAMSON: A team versus a physical  
5 presence. They are not necessarily identical  
6 concepts.

7 CHAIRMAN CERQUEIRA: Well, I think that  
8 some of the things that have been brought up are that  
9 basically you still have the team of three, but only  
10 require two of them to be there if you had a radiation  
11 oncologist available to provide issues related to  
12 treatment and everything.

13 MR. GRAHAM: Well, maybe as a lay person  
14 to help me as I am trying to shape this going around  
15 the room. Most of us are sitting here out of  
16 organizations that are gargantuan, and we have huge  
17 resources, and we are almost looking at this from the  
18 wrong part of the paradigm or potentially.

19 I need to know if at a 350 hospital that  
20 does cardiology, and they do interventional  
21 cardiology, and let's shape it that they don't even do  
22 radiation oncology, and it is two o'clock in the  
23 morning, and the patient is coming in, and the opinion  
24 is that the person needs to have plastic.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701



1                   And they have a history that reflects that  
2                   they may need to have radiation as part of it. I need  
3                   some guidance on what this group is recommending we  
4                   are going to do for that very typical community  
5                   hospital.

6                   Now, if the assessment is that they ought  
7                   to get shipped to a big referral center, which we all  
8                   represent, I guess we at least have to acknowledge  
9                   that there is a certain bias in this discussion, or we  
10                  have to make sure that we have clarified exactly why  
11                  they have to go to that type of center.

12                  CHAIRMAN CERQUEIRA: Well, maybe we should  
13                  address this issue, and I think Dr. Nag and Dr.  
14                  Brinker want to say something as to that.

15                  DR. NAG: Sure. I think I will address  
16                  that very issue two ways. Number One, it is  
17                  theoretically possible what you have just proposed.  
18                  The problem is that a small hospital of that size,  
19                  one, will not be allowed to do intervascular  
20                  brachytherapy because the company that controls  
21                  intervascular brachytherapy are only going to make it  
22                  available to a center that has these backups, and  
23                  small hospitals would not even have this.

24                  MR. GRAHAM: Let me just clarify. The  
25                  market would demand that they would want to be able to

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 provide it to that hospital, because what I have  
2 described is the predominant market in the United  
3 States. We, the big centers, are not the predominant  
4 market.

5 MR. WILLIAMSON: I think to give  
6 technically advanced radiation therapy to any site, be  
7 it neoplastic or benign, you have to have the  
8 appropriate infrastructure in the hospital. Would you  
9 give radiation therapy in a hospital that didn't have  
10 any physicists or radiation oncologists?

11 DR. NAG: That was the second part to my  
12 discussion.

13 CHAIRMAN CERQUEIRA: Let's try to keep the  
14 discussions focused.

15 DR. NAG: That was the second part to  
16 mine, and the second part was, number one, that the  
17 cardiology companies are not interested in giving that  
18 technology to a smaller tertiary center, but the  
19 second part is that to have this done safely and  
20 effectively, it has to be done in a tertiary center  
21 that is doing a lot of these per month, and not one a  
22 year.

23 I would never go to a place that is going  
24 to do this one a year. It is just like having heart  
25 surgery through a tertiary center that is going to do

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 very few of them. And it is very well known that  
2 there is a very sharp learning curve, and no one wants  
3 to be in a tertiary center that is going to have a  
4 learning curve.

5 CHAIRMAN CERQUEIRA: That may be more an  
6 issue of the practice of medicine than radiation  
7 safety. Dr. Brinker.

8 DR. BRINKER: Right. A couple of things.  
9 One thing is the size of the hospital doesn't  
10 necessarily relate to the size of the interventional  
11 population that is being done. Some of the smaller  
12 hospitals are basically heart mills if you will.

13 On the other hand, I would agree that no  
14 hospital should under the present circumstances  
15 undertake intervascular brachytherapy without the full  
16 compliment of backup. And what will happen in these  
17 smaller hospitals is the same way these smaller  
18 hospitals manage to get cardiac surgery to support  
19 their interventionalists.

20 They will contract and make arrangements  
21 to have radiation oncology and medical physicists to  
22 do the same sort of support. So the answer to your  
23 first question is that if a hospital doesn't have  
24 brachytherapy, and a patient comes in with unstable  
25 angina, well then the treatment is to do regular

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 angioplasty most likely, and then either ship the  
2 patient out for further therapy.

3 But we have to remember that  
4 interventional brachytherapy isn't an emergent  
5 treatment for unstable angina. The first part of the  
6 procedure is the angioplasty, and then the adjunct is  
7 intervascular brachytherapy to limit the likelihood of  
8 a future restenosis.

9 So I think that what will happen in most  
10 of these little tertiary hospitals is that they are  
11 not going to say, oh, you have a stent, and you may  
12 have a problem. Go to a tertiary care hospital, and  
13 they will take them to the cath lab, and they will  
14 probably open up the artery if the patient is truly  
15 unstable, and then let things go from there.

16 And you were also right, too, that the  
17 small hospitals with the significant angioplasty  
18 patient volume will want and will be supplied  
19 brachytherapy support, and they will get the full  
20 contingent of people.

21 Again, what I am asking is to think  
22 progressively, and allow sites that have three groups  
23 that want to work together explore ways to do this in  
24 a safe and efficient manner. That's all.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 CHAIRMAN CERQUEIRA: Let me just go back  
2 to get some comments from people that have not  
3 commented. Lou, do you have any -- you are at a big  
4 tertiary center like the rest of us.

5 MR. WAGNER: We do a lot of these  
6 procedures, and I have not been involved directly with  
7 any of these procedures. What I hear around the  
8 table, and what I can surmise is the following. First  
9 of all, I do know that in Europe they are doing things  
10 a little differently.

11 And I have talked to some of the people,  
12 and some comments have come to me that in Europe they  
13 are the Marlboro Boys, and some of the physicists  
14 don't like what is going on over there.

15 We don't know what the outcome is going to  
16 be, but I think that is going to be some experience.  
17 I think the team approach with three people or  
18 individuals is great, but let's think a little bit out  
19 of the box here.

20 Every place you go, you have different  
21 situations. You don't always have the same situation  
22 at this institution or that institution, or any other  
23 institution. Now, the qualifications of the  
24 individuals do vary, and the real issue here is

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 competency in performing the procedures safely. That  
2 is the real issue.

3 Now, what I think Dr. Brinker is asking,  
4 and I don't think it is unreasonable, is that you look  
5 at the team approach, and you require a team, but you  
6 let the team decide whether or not they have the  
7 competency amongst them to be able to perform this in  
8 certain different variations of the same thing.

9 Let the team decide that. They are  
10 medically competent, and radiation safety competent,  
11 and they have the team approach there, and maybe in  
12 some circumstances with the competency that is  
13 available maybe only two have to be necessary in the  
14 middle of the night.

15 Maybe in the middle of the night that's a  
16 safer situation because you don't have the public all  
17 around, and you don't have exposure, potential  
18 exposure to the public because of some of the sources  
19 that you might choose. That is an issue.

20 And that is an issue with all of the State  
21 agencies. They want to make sure that the public out  
22 in the halls aren't going to be exposed too much. I  
23 mean, this is the situation.

24 So maybe the team ought to be given a  
25 little more freedom to look at themselves and they

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 have to agree how they are going to manage their  
2 patients given their resources, rather than to sit  
3 here and decide on micromanagement of every  
4 institution by regulation.

5 The regulation says you have to have a  
6 team approach, and then give them a little bit more  
7 freedom. I tend to see that as a little bit of  
8 thinking out of the box, and some kind of new  
9 concepts, rather than to try and debate this issue as  
10 a yes or no answer at this point.

11 CHAIRMAN CERQUEIRA: Those are very good  
12 points, Lou. Jeff, we will come back to you, but  
13 Sally, do you have from the perspective of a nuclear  
14 pharmacist any input?

15 DR. SCHWARTZ: Nuclear pharmacy at this  
16 point I don't think is a relevant issue. I mean, I  
17 work at the same institution as Jeff, and a team  
18 approach is certainly what we use. I think whether  
19 there is 2 or 3 again depends on how --

20 CHAIRMAN CERQUEIRA: On the situation and  
21 the competence of the individuals.

22 DR. SCHWARTZ: Yes.

23 CHAIRMAN CERQUEIRA: Does the FDA have any  
24 issues that may be relevant to this?

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 MR. HEATON: I have some comments on some  
2 earlier remarks that I thought I heard.

3 CHAIRMAN CERQUEIRA: Okay.

4 MR. HEATON: The remark I thought I heard  
5 was that people didn't consider it any different if  
6 they were giving radiation to the vascular system or  
7 to the neoplastic system, or to something else.

8 The FDA considered this to be a  
9 significant risk for it to go through the 510(k)  
10 route. So the FDA does consider radiation to the  
11 vascular system to be different than if you are  
12 delivering it to the prostate, for instance.

13 MR. WILLIAMSON: I said in terms of  
14 physical safety and quality assurance.

15 MR. HEATON: Well, even with safety  
16 issues, remember that we are evaluating safety and  
17 effectiveness of the device. So safety is a big  
18 concern, at least as far as the FDA defines safety in  
19 there.

20 I will tell you that I have a lot of  
21 safety issues with delivering radiation to the  
22 vascular system that I do not have with delivering it  
23 to the prostate.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701



1 DR. NAG: Are you talking about basic  
2 safety, or are you talking about radiation safety  
3 issues?

4 MR. HEATON: Well, if you are trying to  
5 divide the two, I am talking about patient safety.

6 DR. NAG: And I tried to divide the  
7 radiation safety that is managed by the NRC, and the  
8 basic safety issue, and the medical safety issue.

9 MR. HEATON: I was talking about the  
10 patient safety issue.

11 DR. NAG: I agree with you completely.

12 CHAIRMAN CERQUEIRA: Any other comments?

13 MR. HEATON: Well, I will say that for at  
14 least IDE States for interventional IDEs, they are  
15 still going to require a team approach for any new  
16 studies that do come in.

17 CHAIRMAN CERQUEIRA: And IDE stands for?

18 MR. HEATON: Investigational Device  
19 Exemption, which is what a State has to go through to  
20 get a PMA, or premarket approval application.

21 CHAIRMAN CERQUEIRA: Okay. Good. John.  
22 Ruth, any comments?

23 MS. MCBURNEY: I think that the -- well,  
24 I have liked what I have heard on some flexibility and

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 the team approach, as long as each area of expertise  
2 is covered.

3 And when we look back at who does what,  
4 not necessarily those particular people have to do  
5 that if some of the other people have the expertise in  
6 that area.

7 And it could be that not everybody has to  
8 be physically present during the entire procedure in  
9 some cases.

10 CHAIRMAN CERQUEIRA: Now, Ruth, in terms  
11 of the agreement States, have you gotten any feedback  
12 at the national meetings, in terms of is there  
13 variation in the way that States are handling it, or  
14 is it too early for --

15 MS. MCBURNEY: Well, I think it is too  
16 early to look at what has been proposed in the new  
17 rules. We have already in our State already included  
18 a lot of the requirements for the hodos (phonetic)  
19 remote after loaders that are contained in the new  
20 rules, in our rules.

21 And we are already getting requests for  
22 exemptions from the medical physicists having to be  
23 present during the entire treatment, because in some  
24 small hospitals that only use part-time physicists  
25 from another city, for example, they don't want to

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 have to be going back several days in a row for  
2 sequential treatments.

3 And if they get it set up and an  
4 authorized user is present, and saying, no, the rules  
5 are that the physicist has to be there, too,  
6 throughout the treatment. So we will just have to  
7 live with the rule for a while and see how that is  
8 going to work.

9 CHAIRMAN CERQUEIRA: And you have not  
10 gotten any other feedback about how other States are  
11 handling it?

12 MS. MCBURNEY: No.

13 CHAIRMAN CERQUEIRA: Okay. Naomi.

14 DR. ALAZRAKI: Just that I would again  
15 urge that we not be so prescriptive about this. It is  
16 the practice of medicine. I think the team approach  
17 is important, particularly since it is still an  
18 evolving and new technology, and I think that  
19 radiation oncology is a rapidly growing field.

20 I mean, I think they can hardly keep up  
21 with just the increase in the numbers of cancer  
22 patients involved in radiation oncology, and that  
23 field is going to grow.

24 And they are going to be able to meet the  
25 staffing needs ultimately, I think, and things may

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1        evolve as Dr. Brinker says, and we will be in a  
2        different ball game.

3                But right now we are in the beginning of  
4        it, and I think we ought to stick with this team  
5        approach, and not be very prescriptive about who has  
6        to do what when.

7                CHAIRMAN CERQUEIRA: Finally, Nekita, as  
8        a patient advocate.

9                MS. HOBSON: Well, I guess my question  
10       would be are there any data available that would  
11       demonstrate to us the relative risks to the patients  
12       in two scenarios, and let's say in the emergency  
13       situation that Jeff was talking about, is the patient  
14       better off to have the one very highly trained person  
15       do a procedure, or wait until Tuesday afternoon three  
16       days from now when the full team can be together.

17                Where does the patient come out on this?  
18       I mean, we are talking about real people, and not just  
19       sort of theoretical people. If it were you or your  
20       mother, how would you want to be treated or her to be  
21       treated?

22                CHAIRMAN CERQUEIRA: Well, as a clinical  
23       cardiologist, I think most of the time that you need  
24       to do things quickly and certainly with a lot of these

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 patients who come in that are unstable, the sooner  
2 that you can initiate the treatment, the better.

3 There are some delay techniques that you  
4 can use, but it is probably not optimal treatment,  
5 certainly from my perspective.

6 MS. HOBSON: So in that case, I would like  
7 to have something like where some exceptions could be  
8 made based on an emergency situation, rather than be  
9 bound by rules that are theoretically intended to  
10 protect patients. But maybe in this case are actually  
11 damaging patients.

12 CHAIRMAN CERQUEIRA: Maybe one last set of  
13 comments. I have not heard John speak up with  
14 emotion, although I did note that he was scribbling  
15 things. I don't think we are really at that point,  
16 and Fritz, has this discussion been helpful?

17 MR. STURZ: Well, what I am hearing is  
18 that it is too early in the game, and we have got to  
19 keep with the team approach, but maybe there might be  
20 some flexibility to say 2 out of 3 have to be present  
21 in emergency situations, with a third on call.

22 That is my overall impression of what I am  
23 hearing, and to allow that flexibility in certain  
24 emergency cases.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1                   CHAIRMAN CERQUEIRA: Why don't we go to  
2 Lou, Jeff, and then John has the last word, and then  
3 we will move on to the next subject.

4                   MR. WAGNER: Very briefly, and in  
5 brachytherapy, Jeff, you have been comparing the  
6 oncology with regard to this kind of treatment in  
7 cardiology.

8                   But do you have the emergency situations  
9 that develop on a frequent basis in oncology, or are  
10 most of your brachytherapy assistance planned, where  
11 everybody knows what time it is going to be, and it is  
12 going to be here.

13                  And are you experienced in the idea of  
14 meeting with an emergency when you have the patients  
15 arrive at your hospital and they need treatment right  
16 way, and then you have to have people on call come in  
17 immediately to do that.

18                  I mean, I seem to think in my naive  
19 imagination as a diagnostic physicists that there is  
20 probably a huge difference here with regard to  
21 exigency of the procedure, which is really what the  
22 issue comes down to, and then that comes down to care  
23 of the patient.

24                  CHAIRMAN CERQUEIRA: Let Dr. Nag make one  
25 comment, and then Jeff.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 DR. NAG: Well, I am on call all the time  
2 because of the same thing. I have been doing emergency  
3 intervascular brachytherapy radiation all the time.

4 The surgeon would go in and they would try  
5 to take out the tumor, and we wouldn't even know about  
6 it, and all the while the patient is wide open, and  
7 can you come up and radiate the tumor bed, and we  
8 would be up there in 15 minutes to 20 minutes.

9 So it is our response time and it is much  
10 faster than any response time that I have needed to  
11 give to my cardiologists, because cardiologists  
12 usually are much better, and they give me more than a  
13 few hours notice.

14 I have the time to even talk to the  
15 patient beforehand, and many of the emergency patients  
16 I have talked to, and I have put the catheter in  
17 first, and talked to the family, and so our response  
18 time --

19 CHAIRMAN CERQUEIRA: Those are good  
20 points, although I guess some of the situations that  
21 Dr. Brinker was referring to was that most oncology  
22 surgeries are elective, and a lot of the cardiac  
23 problems with unstable patients are in a more random  
24 manner.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 DR. NAG: You probably need a better set  
2 of radiation oncologists in your hospital.

3 DR. BRINKER: We have a very good set of  
4 radiation oncologists, but believe me in all honesty,  
5 when you are doing a hundred procedures a week, and  
6 you are doing them 24 hours a day and on weekends, it  
7 is a major commitment, especially since some radiation  
8 oncologists -- and you may be one of them -- feel that  
9 they have to see every patient before the procedure.

10 That is impossible, because they would be  
11 seeing 10 patients for every two that actually need  
12 this procedure, even if they could see every patient.  
13 So clearly unless you feel there is some inefficiency  
14 and that the whole house of cards is going to fall  
15 down.

16 CHAIRMAN CERQUEIRA: Okay. One last  
17 comment from Jeff, and then we will go on to the next  
18 item.

19 MR. WILLIAMSON: I think this whole  
20 discussion has been rather diffusely and not very  
21 targeted on what the issue is. I think with the  
22 exception of one comment, and maybe John meant it  
23 rhetorically, I don't think that anybody has set that  
24 there should not be a team approach.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701



1           That there does not need to be in the  
2     structuring and organization of this procedure all  
3     three types of individuals being involved, and I think  
4     the discussion should be focusing on who needs to be  
5     where when, and does team approach necessarily mean  
6     all three people have to be in the operating room from  
7     the start to the end of the treatment.

8           And again I think I will go back to the  
9     way the existing regulations are written, 400 and 600,  
10    and they are sort of graded based on response time,  
11    technical complexity, and I forgot to mention -- and  
12    this is important, too -- the public health  
13    consequences of an uncontrolled source.

14           So Beta and Manual Iridium pose much  
15    smaller risks than if you have a 12 query or high dose  
16    rate source running loose. I really think they are  
17    different, and I think that the sort of graded level  
18    of physical presence needs to be carefully calibrated  
19    to that, and so I really agree with the idea of  
20    flexibility --

21           CHAIRMAN CERQUEIRA: I think basically  
22    that the team approach with flexibility, with some  
23    encouragement to make 2 of the 3 present in some  
24    situations where you can't do things electively, and  
25    there is a certain urgency. Those are good points,

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 but I think we really need to go on to the next  
2 subject.

3 MR. WILLIAMSON: Well, to just sort of  
4 finish my last comment, I think there is a lot of  
5 guidance in the existing regulations where those  
6 boundaries fall, and who needs to be where when.

7 CHAIRMAN CERQUEIRA: Good. Excellent.

8 MS. HOBSON: But not to withhold urgently  
9 needed treatment based on some rule. I mean, not that  
10 the rules are bad, but if they are a stumbling block  
11 to good patient care, then they are not doing their  
12 own job.

13 CHAIRMAN CERQUEIRA: Okay. We will give  
14 Nekita the last word, and we will go on to the next  
15 topic. Fritz, thank you very much, and the next item  
16 is Authorization for Broad Licensees to Utilize New  
17 Brachytherapy Procedures. John Hickey. So we have  
18 not really left it yet have we.

19 MR. HICKEY: Good afternoon again. I  
20 don't have a visual presentation. I do have a one  
21 page summary. Much of this was discussed in the last  
22 meeting, but I kind of wanted to try to clarify and  
23 bring this to closure.

24 We want to talk about broad licensees, and  
25 they by definition are not restricted in the way that

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 limited specific licensees are and how they use  
2 radioactive material for medical purposes.

3 They have a radiation safety committee and  
4 other management, and procedures in place to evaluate  
5 authorizations for various uses, and so that gives  
6 them broad flexibility.

7 When we came up to these newer procedures,  
8 we found that even for broad licensees that we needed  
9 to take a look at how these were authorized, because  
10 again the traditional brachytherapy envisioned using  
11 sealed sources to treat cancer.

12 And now we are finding that liquids and  
13 gases might be used for that purpose, and also that  
14 there would be treatments for intervascular  
15 brachytherapy and not just for cancer.

16 So to some extent, Part 35 didn't quite  
17 fit the situation, and with respect to the broad  
18 licensees, in most cases it didn't matter. But we  
19 found that it did matter in some cases how Part 35 was  
20 worded, particularly with the requirement to prepare  
21 a written directive.

22 And I noted Dr. Wagner's comment earlier,  
23 I believe, that just the fact that you get into having  
24 to prepare a written directive causes a prescriptive  
25 aspect to the regulation. So here is an example of

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1       where this could get you into a more prescriptive  
2       mode.

3               So we took a closer look at this, and to  
4       some extent we asked and answered several questions,  
5       and taking into account the advice of the committee  
6       from the last meeting.

7               And that is that for these new types of  
8       technologies, where there may be some little wrinkles  
9       that need to be considered, how much flexibility  
10      should the broad licensees have.

11              And our conclusion was that we should  
12      -- that if it is in a gray area, make the decision on  
13      the side of giving the broad licensees -- and in  
14      general licensees, but in this case broad licensees  
15      more flexibility rather than less flexibility, and  
16      that is consistent with having a more risk informed  
17      performance based approach.

18              So if there is a little bit of a twist on  
19      how they had to prepare the written directive, we are  
20      going to leave that up to the broad licensee. We are  
21      not going to have them come in and get NRC approval on  
22      how to prepare a written directive every time they get  
23      a new technology.

24              And the New Part 35 is worded accordingly.  
25      And we have also -- and a couple of examples would be

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1       for -- well, there are a couple of areas in the  
2       current Part 35 where you don't have to specify the  
3       treatment site in advance in preparing the written  
4       directive.

5               And that has been clarified in the New  
6       Part 35. Also, it assumes that you are treating with  
7       a certain number of sources or source strengths, and  
8       again that assumes a sealed source.

9               But if you are dealing with a liquid or  
10       gas, that doesn't quite fit. So you could express the  
11       treatment in terms of the total source activity,  
12       rather than worry about how many sources.

13               So that is the general approach we are  
14       going to take, and we think that is consistent with  
15       the advice of the committee.

16               CHAIRMAN CERQUEIRA: I will open it up for  
17       discussion. Dr. Nag.

18               DR. NAG: I agree with you, but the way  
19       that the New Part 35 definition is on your paper,  
20       before a implantation in the treatment site, the  
21       radionuclide and the dose, I think that it shouldn't  
22       be and the dose, because we may or may not know the  
23       dose beforehand.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1                   It could be "and/or dose activity."  
2       Because if we do a permanent implant, we won't know  
3       the dose. That should be corrected.

4                   MR. HICKEY: Let me double-check that for  
5       you, but we can continue the discussion. I have the  
6       text right here. Go ahead.

7                   CHAIRMAN CERQUEIRA: Sure. Other items of  
8       discussion for John?

9                   MR. WAGNER: I think it is great. End of  
10      discussion. I think it is great.

11                  CHAIRMAN CERQUEIRA: It's great. Anybody  
12      opposed to that? Jeff, you are happy with it?

13                  MR. WILLIAMSON: Well, let me just ask.  
14      This New Part 35 definition is the one that is in the  
15      Part 35 that is before OMB now?

16                  MR. HICKEY: Correct.

17                  MR. WILLIAMSON: Word for word?

18                  MR. HICKEY: That is what I am talking  
19      about, but I am checking the wording now.

20                  DR. NAG: And in that case, even after  
21      that the --

22                  MR. WILLIAMSON: I think you have to go to  
23      the definition section and see what dose says. I  
24      can't remember if it is in the New or Old Part 35, but

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 I think it says or that it may define dose as the  
2 product of source intensity and treatment time.

3 And that is sort of important I agree,  
4 because some treatments are not prescribed in terms of  
5 physically absorbed dose, but they are prescribed in  
6 terms of total reference, the product of source,  
7 strength and time.

8 DR. NAG: And even here after  
9 implantation, you still have the number of sources  
10 which may or may not be applicable.

11 MR. HICKEY: Forgive me, but just to  
12 clarify. You are correct, Dr. Williamson. The dose  
13 can be the total source strength and exposure time, or  
14 the total dose.

15 DR. NAG: Okay. And then after  
16 implantation? Again, here you would take treatment  
17 site, number of sources, and again that may or may not  
18 apply.

19 MR. HICKEY: Correct. That's where we  
20 give a little bit of leeway in specifying source  
21 activity rather than number of sources, depending on  
22 the application.

23 CHAIRMAN CERQUEIRA: Okay. So anybody  
24 else wish to make comments? Well, that's good. We

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 are ahead of schedule. Maybe we should try to just  
2 keep going now to additional items.

3 MR. HICKEY: Well, I have a question on  
4 the previous topic, and I apologize, because we went  
5 overtime. But I noticed that there was still some  
6 discussion going on, and my question is -- if the  
7 chairman will indulge me.

8 CHAIRMAN CERQUEIRA: Sure.

9 MR. HICKEY: And it has to do with the  
10 team approach, which assumes that the interventional  
11 cardiologist is not an authorized user. We think in  
12 the future that we are going to reach the point where  
13 the cardiologists are also authorized users.

14 So my question is what does the committee  
15 envision as -- how do we define or describe the role,  
16 or what is our concept of who the interventional  
17 cardiologist is, and I am looking at this from the  
18 point of view of a regulator.

19 I am describing the members of the team,  
20 and so if the interventional cardiologist is not the  
21 authorized user, what is the role or how do we define  
22 who that is?

23 CHAIRMAN CERQUEIRA: Anybody care to  
24 answer that?

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701



1 MR. WILLIAMSON: Do you mean functionally  
2 what is the authorized users purpose; is that what you  
3 mean?

4 MR. HICKEY: No, this is -- if there are  
5 people there -- the medical physicist and the  
6 authorized user are defined by the regulation. The  
7 interventional cardiologist is not there. So if we  
8 are going to put out guidelines that assign a role to  
9 the interventional cardiologist, how are we going to  
10 define who that is or describe who that is?

11 DR. VETTER: I don't think the NRC should  
12 do that. That is a medical problem and the team will  
13 certainly -- I mean, they have to involve the  
14 cardiologist, but that should be left up to the  
15 medical center on how they want to define that team,  
16 and who that interventional cardiologist is.

17 DR. DIAMOND: We are going to give Lou a  
18 stroke.

19 MR. HICKEY: Then do we need to mention  
20 the interventional cardiologist at all in our  
21 guidance?

22 CHAIRMAN CERQUEIRA: I think Dr. Diamond's  
23 point was that it may be a cardiologist, but it could  
24 be an interventional radiologist in some cases. So  
25 you need sort of a -- you know, a physician who has

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1       been approved to do the procedure, which is really  
2       sort of a hospital --

3                   DR. ALAZRAKI:   Purview.

4                   CHAIRMAN CERQUEIRA:   Right.  I mean, they  
5       decide who has privileges to be in a cath lab to do  
6       interventional radiology procedures.  You know, the  
7       issue may come up, and which really relates to this  
8       committee, is that if you are going to allow  
9       radiologists to be the authorized users, then what  
10      sort of training should they have.

11                  But we have kind of decided that at this  
12      point it is still a team approach, but these other  
13      issues of the requirements for the non-authorized user  
14      involved in the case, I think that is defined by  
15      hospital requirements, and by professional medical  
16      societies, and shouldn't really be defined by the NRC.  
17      Ruth.

18                  MS. MCBURNEY:   Well, going back to what  
19      expertise is needed, and you have that list, and you  
20      have patient preparation, and introduction of the  
21      source train, and the removal being the responsibility  
22      of the interventional cardiologist, without naming  
23      that person by name, someone that has the expertise to  
24      do that as part of the whole procedure would be  
25      appropriate.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 DR. NAG: I would like to respond to that.  
2 Since very soon this will be both in the cardiac, as  
3 well as in the vessels, instead of naming  
4 interventional cardiologists, you can call them  
5 interventional physician, or intervascular physician.  
6 That will be open to anybody, number one.

7 And, number two, on Mr. Sturz's list, I am  
8 aware that at most hospitals the introduction of the  
9 source and the removal of the source train is not done  
10 by the interventional cardiologist. It is done by  
11 radiation oncologist. So that's why from what has  
12 been shown, I ask you how or where did you get this.

13 CHAIRMAN CERQUEIRA: Jeffrey.

14 MR. WILLIAMSON: I have a question for the  
15 two cardiologists. To what extent do you use Fellows  
16 and Trainees who are not board certified in  
17 interventional cardiology to do procedures, and do you  
18 insist on physical presence when you are there all the  
19 time?

20 Do you allow them to do procedures when  
21 you are not physically present? For example,  
22 somewhere else in the hospital. This is an  
23 informational question, and I really don't know,  
24 because as you can see, when you become an authorized

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 user it becomes a major struggle of who can  
2 substitute.

3 CHAIRMAN CERQUEIRA: At our institution  
4 the requirements are that you have to be approved by  
5 the -- we have a cardiac catheterization committee  
6 that approves who can do procedures by themselves, and  
7 Fellows don't qualify.

8 So we have an attending present at all  
9 times in the cath lab. I don't know what it is like  
10 at Hopkins.

11 DR. BRINKER: There is always an attending  
12 physician scrubbed with a Fellow, or a Physician's  
13 Assistant sometimes assist in these procedures.  
14 Fellows do not do interventional procedures by  
15 themselves, nor now do they even do diagnostic  
16 catheterizations by themselves without a scrub  
17 attending at the table.

18 There are two reasons for this. The first  
19 reason is patient safety, and the efficiency of the  
20 whole system, as well as teaching of the fellow; and  
21 the second system, which is possibly a little bit  
22 related, is the fact that Medicare insists that the  
23 attending physician was scrubbed and at the procedure.  
24 So that sort of makes life easier.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1                   MR. WILLIAMSON:   So then you could use  
2 board certification as a defining --

3                   DR. BRINKER: Well, board certification is  
4 very antsy in cardiology for a couple of reasons.  
5 First of all, there is a new interventional board  
6 which not every interventionalist has taken yet.

7                   And that there are qualified physicians  
8 who have finished Fellowship, and who even have not  
9 been board certified in cardiology yet, but who have  
10 the ability to perform independent catheterizations.

11                  So boarding is not -- and unlike the  
12 things that we heard earlier for other specialties,  
13 boarding is not a qualification or a necessity for  
14 physicians to do either catheterization or  
15 interventional procedures.

16                  CHAIRMAN CERQUEIRA: Does that answer your  
17 question?

18                  MR. WILLIAMSON: Yes.

19                  CHAIRMAN CERQUEIRA: All right. At 2:30,  
20 we are supposed to discuss additional items.

21                  MR. HICKEY: Yes. Dr. Wagner wanted to  
22 introduce this topic if he could.

23                  CHAIRMAN CERQUEIRA: Sure.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1           MR. HICKEY: I would like to remind  
2 everybody that I believe that this is your last  
3 meeting, Dr. Wagner.

4           MR. WAGNER: Yes, my last meeting, and so  
5 I want to leave you with a little more work. There is  
6 a handout coming around with regard to two issues,  
7 which I think the ACMUI ought to start considering  
8 with regard to advice to the NRC on some issues.

9           And they have all come up because of the  
10 changing times, and I want to bring them to your  
11 attention. I thank the NRC and the Chair for giving  
12 me this time to present this.

13           I am not presenting this as something that  
14 I think we ought to discuss here and now, but I am  
15 presenting this as something as issues that I think  
16 are going to be future issues to address, and trying  
17 to get the ball rolling on some of these things.

18           For example, Issue Number One, Part 20  
19 exposure limits apply to all types of radiations, and  
20 not just to those generated by-product materials.

21           This is a problem in medicine. Many  
22 physicians perform nuclear medicine procedures and  
23 fluoroscopy interventions. So we are mixing now x-  
24 rays with by-product material radiation.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1           An effective dose equivalent is usually  
2           the limit that is applied, but it is impossible to  
3           measure. Anybody that thinks that they can measure  
4           accurately the effective dose equivalents is  
5           misguided. This is not something that is possible to  
6           do.

7           So how does the NRC and agreement States  
8           apply limits to individuals who mix exposures? This  
9           is a major problem. So now we need reform in methods  
10          of occupational risk assessment, and enforcement,  
11          because basing violation type enforcement on a mixed  
12          EDE that is impossible to measure is totally  
13          impractical.

14          It is not a practical solution. The  
15          fallout, and we are all familiar with this, violation  
16          of enforced regulation discourages faithful risk  
17          monitoring. How many physicians sit there and have  
18          told me that you are not going to prevent me from  
19          practicing.

20          I won't wear my film badge, and it is  
21          impossible to go around and make sure that everyone is  
22          wearing a film badge all the time. It is just silly.  
23          We are discouraging these things, and we shouldn't be  
24          doing this.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1                   We want them to wear their film badges,  
2                   and we want to know what the radiation environment is,  
3                   and we don't want regulations that discourage the  
4                   practice of medicine.

5                   So we need to develop techniques that  
6                   reward good practices of risk monitoring. We need to  
7                   change things. Now, this has been stimulated by  
8                   certain messages that have come across my E-mail  
9                   recently, where these issues are becoming problems,  
10                  and it is quite clear that problems are being raised.

11                  And certain bodies might calculate  
12                  effective dose equivalent one way, and other bodies  
13                  might calculate it another way, and they all come up  
14                  with different numbers.

15                  I mean, it has gotten to a point of  
16                  silliness in some regards. I know that the State of  
17                  Texas used to have a rule -- and I don't know if it is  
18                  still there because they have changed the rules so  
19                  many times recently, but there was a rule where if you  
20                  exposed a physician to more radiation, you could  
21                  legally lower his dose.

22                  I mean, there was a rule, and they had  
23                  that in there, and you could lower our dose  
24                  significantly by exposing yourself to more radiation,  
25                  because you crossed the boundary and now you could

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701



1       apply a different rule of calculation.       Total  
2       silliness, okay, for things that aren't uniform.

3               So my recommendation is that the NRC  
4       should review its rules on occupational dose  
5       limitation to determine, one whether the NRC has legal  
6       authority to incorporate risk from non-by-product  
7       material into their regulations.   That's number one.

8               And, number two, to investigate risk  
9       informed methods of regulation based not on dose  
10      limits and numbers that are generated and meaningless,  
11      but on practice of risk assessment and an informed  
12      work force.

13              It is a new concept and it is a new idea  
14      that I wanted to put forth to this committee.   The  
15      idea that numbers aren't what is really important to  
16      generate.

17              What is really important to look at is  
18      whether nor not the facility has a significant risk  
19      assessment method in practice, and they are using it  
20      properly to inform the work force about what they are  
21      being exposed to.   That's really what is important.

22              So that is the first issue that I wanted  
23      to raise and bring to the committee's attention.   I  
24      think it needs to be addressed.   My second issue is  
25      that conditions for licensing are specified by

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1       licensing agency and are listed on the license. This  
2       is a fact and we are all familiar with this.

3               Regulations state that an agency may  
4       require conditions to ensure safety. That is  
5       perfectly sensible; and conditions or regulations that  
6       are not subject to public review. That's a fact, that  
7       are put on your license by the agency.

8               But now I ask who in the agency decides on  
9       conditions, and what guidance is followed to ensure  
10      uniformity, and are the conditions risk based. I  
11      think these issues ought to be addressed, because it  
12      is a way that the risk based rules can be  
13      circumvented.

14              I would like to recommend that the NRC  
15      review its policies in creating licensing conditions  
16      and make modifications as necessary.

17              And define criteria under which conditions  
18      are necessary; i.e., things like the uses uncovered by  
19      the rules, or the facilities to have repeat  
20      violations. These would be the criteria by which a  
21      condition would be imposed.

22              Number Two, to ensure that the conditions  
23      are risk based and not just arbitrary. And, three, to  
24      ensure uniformity and fairness in requiring licensing  
25      conditions.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1                   Now, this was brought up by several issues  
2                   that I had experience with. One is that we have a  
3                   meeting in Houston, Texas, amongst radiation safety  
4                   officers at our facility. We are a huge medical  
5                   center, and we have an enormous number of radiation  
6                   safety officers all congregated with a couple of  
7                   square miles.

8                   And we get together and we talk about  
9                   these things, and we found out that different  
10                  facilities are treated differently, and that all of  
11                  the conditions are different, and it all depends on  
12                  who you had as an oversight or overseeing your license  
13                  when it was made up.

14                  I just had a recent situation where a  
15                  condition was put on our license, and it was  
16                  arbitrarily put in there. We asked why and he said  
17                  because I don't believe that you are going to do what  
18                  you say you are going to do. I want you to do this  
19                  extra thing.

20                  And then we asked, well, this is in the  
21                  rules that we stated in our policy and procedures, and  
22                  why do you want us to do this extra documentation.  
23                  You know, it is not necessary and we don't want to do  
24                  this. This is silly.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1           And the idea was, well, maybe if you  
2           discussed it with us for a couple of months, and we  
3           might get around to agreeing with you. But if you  
4           want it approved right away, you had better agree to  
5           it. This was a problem. I didn't see this as fair.

6           And then it was brought up again in the  
7           letter by the Society of Nuclear Medicine and the  
8           American College of Nuclear Physicians, that these  
9           conditions could be imposed on licenses, and they seem  
10          to have a problem with it.

11          So it seems to be much broader than just  
12          the personal experience. So I think these are two  
13          issues that I think are important to address at this  
14          point.

15          And I think that the ACMUI would be doing  
16          a good service to the nuclear regulatory commission to  
17          try to give some advice with regard to these issues,  
18          because the future of medicine is changing, and it is  
19          changing rapidly, and we need to meet these problems  
20          at this time.

21          CHAIRMAN CERQUEIRA: Thank you, Lou.  
22          Those are very good points. Any comments? Jeff.

23          MR. WILLIAMSON: Well, I think Issue  
24          Number 1 is really very, very important. And in fact  
25          it has been brought into focus at Washington

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 University for the very reason that we were talking  
2 about just earlier, which is intervascular  
3 brachytherapy.

4 The fact that when cardiologists become  
5 involved in the delivery of treatment using by-product  
6 materials, all of a sudden all of their exposures from  
7 floral exposures become subject to Federal oversight,  
8 and this is has actually provided one reason why the  
9 radiation oncologist should be physically present. I  
10 mean, this is one solution.

11 The radiation oncologist can do the  
12 procedure and the cardiologist can step away and then  
13 preserve their ability to avoid Federal oversight.

14 DR. BRINKER: What we really need is the  
15 radiation oncologist to stand between us and the  
16 floral.

17 (Laughter.)

18 MR. WILLIAMSON: Precisely, and as you can  
19 see, there are more creative and clever variations on  
20 this theme, but it is a serious problem, and I think  
21 the fact that it points out that the -- and I think  
22 Lou has a real point here.

23 That there really is an awful lot of  
24 expense, and in some cases maybe loss of quality of  
25 medical treatment needed to satisfy a very arbitrary

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 rule which in many expert's minds has questionable  
2 data behind it.

3 You know, are there such severe risks  
4 associated with personnel exposures, at least to the  
5 point where there should be such adherence to her rule  
6 that 4.99 is okay, and 5.01 is unacceptable.

7 CHAIRMAN CERQUEIRA: Those are good  
8 points. Dr. Nag.

9 DR. NAG: Would you clarify your point  
10 three on your issue number one, or 13, that it would  
11 be impossible to measure the annual .5 that the mixing  
12 exposure -- I mean, I just want to know a little bit  
13 more about that.

14 MR. WAGNER: The effective dose equivalent  
15 is based upon individual organ doses of the body and  
16 it is based upon a waiting factor assigned to each  
17 individual organ dose, and the waiting factor itself  
18 is based upon the proposed radiosensitivity of that  
19 organ, which is based on some very questionable data.

20 So if you are wearing a lead apron in a  
21 fluoroscopy room, and calculating your effective dose,  
22 it is quite different than if you are exposed to a  
23 nuclear medicine source.

24 Furthermore, most of the calculations  
25 don't even take into account body attenuation to

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 internal organs. I mean it is also some arbitrary how  
2 we do this thing, and it is a prescription of how to  
3 calculate a number, rather than to really define a  
4 safety issue.

5 And I think that we are getting away from  
6 that philosophy of having these prescriptive  
7 ridiculous things that don't really achieve what you  
8 are looking at, and let's look at what we are trying  
9 to look at.

10 Let's look at your program of risk  
11 monitoring, and whether or not your risk force is  
12 appropriately informed of the risks they are taking in  
13 the environment that they are working in.

14 CHAIRMAN CERQUEIRA: Jeff.

15 MR. WILLIAMSON: Maybe a question to John  
16 Hickey, and if he could clarify what NRC's  
17 understanding of what Part 20 implies regarding this  
18 issue of non-by product exposures.

19 MR. HICKEY: yes, and this is partly a  
20 legal issue, and I am a technical person and not an  
21 attorney, but the way that Part 20 is worded is that  
22 the total occupational radiation exposure that a  
23 person gets should meet the NRC limits.

24 And that assumes that some of the exposure  
25 is from NRC licensed material. That's how we get into

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 the picture. So if somebody gets, for example, 3 rem  
2 of exposure from accelerators, and 3 rem from NRC  
3 regulated material in a year, then we would be  
4 concerned about that. The intent is the workers'  
5 total exposure should be controlled.

6 CHAIRMAN CERQUEIRA: All right.

7 MS. MCBURNEY: From a State's perspective,  
8 of course the States regulate all sources of  
9 radiation, and so we do have to take into account the  
10 total occupational dose.

11 We have -- and many of the other States --  
12 have incorporated the NCRP recommendations figuring  
13 some sort of EDE when there is an apron present, and  
14 they are wearing a badge both outside and inside the  
15 apron and could calculate that.

16 And so I think we are trying to make  
17 attempts to do that, but in a regulatory arena you do  
18 have to have some sort of limit in the rule, and not  
19 just sort of nebulous, and risk-informed, and you know  
20 the risk, and whatever you get that's okay.

21 MR. WAGNER: With all due respect, Ruth,  
22 I understand that from the point of view of  
23 regulation, but I think we are in a box, and I think  
24 we can think outside of that box.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701



1                   Numbers don't have to be a matter of less  
2                   than no violation, or more than a violation. The  
3                   numbers can be used as limits or guidelines at which  
4                   certain action items are taken, and certain risk  
5                   informed issues are addressed.

6                   But not necessarily that with this number  
7                   that you have not violated and this number you have  
8                   violated the rule. And we can get away from that  
9                   thinking, and we can get more into the thinking of  
10                  using these numbers more as a guidance for advice and  
11                  practice, and whether or not the program that they  
12                  have instituted is a good risk-based program of  
13                  monitoring, and not a matter of number generating.

14                  And really with the numbers and the way  
15                  that they are calculated, and all the numbers that are  
16                  used, whether it is NCRP or not, they are all wrong  
17                  because they are all based upon some badge monitor or  
18                  somewhere on an apron, and then what happens when they  
19                  use a face shield that blocks the badge.

20                  I mean, it totally makes it a ridiculous  
21                  number. So I think we have got to get away from that,  
22                  and I would like to see thinking outside the box now  
23                  for risk based rules, and I think we can get away from  
24                  those numbers.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1                   We don't have to have them, and I think  
2                   there is creative ways to do that and still keep a  
3                   very sane and safe working environment.

4                   CHAIRMAN CERQUEIRA: David.

5                   DR. DIAMOND: Lou, one thing that you  
6                   mentioned was very disturbing to me, and that was your  
7                   second issue, which seemed to me that the colleague  
8                   that you were referring to was the subject of some  
9                   fickle treatment by our regulator that had no real  
10                  basis, no logical basis, and it was almost at a  
11                  punitive nature, or a vindictive nature almost in a  
12                  quality.

13                  And of course that had no potential for  
14                  public review and therefore disputation. That to me  
15                  is the most disturbing thing that you have mentioned  
16                  so far. Is this something that happens on a regular  
17                  basis? Is this an antidotal event?

18                  MR. WAGNER: I don't meant that to be a  
19                  matter of being punitive, or vindictive, or anything  
20                  like that. I don't think that is the motivation. I  
21                  think it is a matter of regulators having a mindset  
22                  about what is important and what is not important, and  
23                  then they apply certain rules.

24                  I didn't know where this new addition was  
25                  coming from and I really was not the direct contact on

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 the issue. I was the guy in the background working  
2 out the issue, okay?

3 And it was a duplicative issue. It was a  
4 matter of forcing additional documentation on a  
5 prescriptive basis every week to ensure that certain  
6 white tests are done, which was already in the  
7 policies and procedures that you do the white tests  
8 every week in the first place.

9 Why did we need this additional  
10 documentation so that the RSO checked to make sure  
11 that they were being done every week and then sign the  
12 documentation that said that. It didn't seem right to  
13 me, but I don't know that it is vindictive or  
14 anything like that.

15 To me, it is arbitrary, and that to me is  
16 the issue. I think uniformity in the application of  
17 these conditions for good reason is what is necessary,  
18 and I want to emphasize that is a State agency, and an  
19 agreement State and not at the NRC.

20 But all of this guidance comes down from the top and  
21 from the NRC.

22 CHAIRMAN CERQUEIRA: Jeffrey.

23 MR. WILLIAMSON: At Washington University,  
24 we have had similar incidents, too, with the NRC, and  
25 this is NRC because we are not an agreement State.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 For example, if your institution is so unfortunate to  
2 commit a violation, what our experience has been is  
3 the inspectors who come and deal with this situation  
4 can actually sort of prescribe punishments that go  
5 well beyond the pale of the rules.

6 So, for example, in one case they ruled  
7 basically that we had to document that we checked the  
8 condition of the implants by an authorized user once  
9 each shift.

10 Now, of course we checked the implants  
11 quite frequently, but there is no requirement in Part  
12 35 that says that we have to document such a check.

13 So they simply made up basically a  
14 prescriptive rule, especially made for us, because  
15 they thought that we needed this extra Federal  
16 oversight. Now, I am certainly not arguing against  
17 carefully checking patient's implants on a periodic  
18 basis.

19 I think that really the NRC has no  
20 authority to be involved in this. Their oversight  
21 should be limited to whether we are following the  
22 rules, and if we have a violation, we of course  
23 honestly report it, and this was a self-detected  
24 event.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1                   So I think it does happen all the time.  
2                   I could mention also licensing experiences, where we  
3                   have had the same thing, especially with a newer or  
4                   untried technology.

5                   There is a tendency to sort of make up  
6                   rules sort of on the fly, or base them on Cobalt 60  
7                   teletherapy, or some existing standard, and then  
8                   inappropriately adapt that standard to the new  
9                   technology.

10                  CHAIRMAN CERQUEIRA: Good. Well, I think  
11                  these are very good points, Lou, that you brought up,  
12                  and I am sure that John Hickey, who is going to be  
13                  coming up to microphone for the next presentation will  
14                  take all of this into consideration, and take  
15                  appropriate actions, right, whatever they may be.  
16                  Well, good.

17                  Let's go on to the next topic, and maybe  
18                  we can cover that before the break, John, and that is  
19                  the rejection of medical waste by local landfills.  
20                  This is an issue that we have discussed before.

21                  MR. HICKEY: Yes, Mr. Chairman, I think we  
22                  should be able to cover this briefly, but I am  
23                  available to entertain questions. I think most of you  
24                  are aware of the general problem.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 Medical licensees and other licensees can  
2 dispose of certain materials that are slightly  
3 contaminated as normal trash, which means that they  
4 can go to a local landfill that accepts general  
5 refuse, or there is also disposal sites that accept  
6 hazardous waste, but not radioactive waste, but it may  
7 be hazardous for other reasons because of its med-bio  
8 hazard contents or whatever.

9 And many waste processors and landfills  
10 have installed radiation alarms as a preventive  
11 measure, because there is all kinds of ways that  
12 radioactive material can get into a disposal facility.

13 So we frequently get reports several times  
14 a week among us and the States of these alarms going  
15 off. And the problem is that the types of waste that  
16 can trigger an alarm can be authorized or  
17 unauthorized, and there is no formula for a radiation  
18 alarm system that can make the distinctions that would  
19 need to be made.

20 In some cases, the authorized versus  
21 unauthorized material cannot be distinguished by a  
22 physical device. In other cases, the sensitivity is  
23 not a determining factor because you could have  
24 material that is shielded, and therefore you would

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 want your alarm to be more sensitive to find material  
2 that is partially shielded.

3 And in some cases the material is very low  
4 contamination, but low levels of radioactivity, but  
5 might still be unauthorized. So they want the alarm  
6 to be in place for that purpose.

7 So we get reports sometimes that the waste  
8 generator is a hospital, and in some cases it was an  
9 unauthorized disposal, and upon review the hospital  
10 says that that should have gone out as radioactive  
11 waste and we let it go out as non-radioactive.

12 But in other cases it was legitimately  
13 disposed of. So the States -- the NRC doesn't  
14 regulate these refuse facilities and in many cases  
15 they are State regulated, but not by the radiological  
16 health people. They are regulated for some other  
17 purposes.

18 So I don't -- we don't see an easy  
19 solution to this. What we have done is encouraged  
20 communication that the hospitals and others need to be  
21 aware of what monitoring systems are in place at the  
22 disposal facilities.

23 And use the same or equivalent monitoring  
24 when the stuff goes out the door so that they know  
25 what is going to pass. And if they know that

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 something is not going to pass, they need to negotiate  
2 that in advance and not just wait until the alarm goes  
3 off.

4 DR. DIAMOND: John, I understand that some  
5 of these systems are very, very sensitive; is that  
6 correct?

7 MR. HICKEY: Correct.

8 CHAIRMAN CERQUEIRA: I have been at  
9 agreement State meetings, and that's a big complaint,  
10 and it is a big expense for the States, because  
11 sometimes for non-hazardous levels of radiation, they  
12 have to go through and find it, and it is very time  
13 and money prohibitive. Jeffrey.

14 MR. WILLIAMSON: What forces the landfills  
15 to set the threshold so low that you are getting these  
16 reports all the time?

17 MS. MCBURNEY: They do themselves.

18 MR. HICKEY: As I said, the material could  
19 be partially shielded. So they are not assuming that  
20 they are looking for unshielded materials. So that  
21 they set it at a state-of-the-art sensitivity. Go  
22 ahead.

23 MS. MCBURNEY: Some of the manufacturers  
24 of these detectors will set the sensitivity

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701



1 themselves, because the landfill owners don't know.  
2 They just say we want to pick up anything that we can.

3 The conference radiation control program  
4 directors has developed some guidance for landfill  
5 operators, and in setting the sensitivity of these,  
6 and made some recommendations. But the landfill  
7 operators don't have to comply with that because they  
8 are not regulated by them.

9 MR. WILLIAMSON: But it would seem that  
10 you wouldn't have to investigate it if it were under  
11 a certain level.

12 MS. MCBURNEY: Well, the landfill operator  
13 would just call and say I have got a hit, meaning that  
14 the alarm has gone off. So the State investigator --

15 MR. WILLIAMSON: Has to run out there and  
16 at a minimum, you have to do a check of the exposure  
17 rate at one meter and decide whether to do anything  
18 else. But you are not forced to do anything more than  
19 that.

20 MS. MCBURNEY: Right.

21 CHAIRMAN CERQUEIRA: Although some of the  
22 States complained that they have to clean it up, and  
23 first of all find --

24 MS. MCBURNEY: You know, first find it,  
25 and then find out if it is just a piece of bed linen

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 or a diaper from a hospital, or if it is a sealed  
2 source.

3 MR. WAGNER: So what are you asking us  
4 for?

5 MR. HICKEY: This was an informational  
6 item primarily, and you are welcome to comment. One  
7 of the members suggested that we discuss this during  
8 the meeting, and so you are welcome to comment.

9 MR. WILLIAMSON: Well, I think this is a  
10 good example of the regulators, or like the regulators  
11 that we have in the regulated community, and our  
12 professional associations make guidance that we make  
13 available, and we try to promote its use, and it is a  
14 really good thing to do.

15 And maybe that would be the only long term  
16 strategy, but a question that I have is what is the  
17 level of compatibility of 35.75, which I assume must  
18 be contributing to a lot of this.

19 And a follow-up question to that is how  
20 much of this is due to the change in the patient  
21 release rule?

22 MS. MCBURNEY: If it is coming from the  
23 hospital, it is not due to release of patients. It is  
24 due to their normal nuclear medicine waste. Now, we  
25 in Texas have a unique rule that allows certain

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 concentrations of short lived material that is less  
2 than 300 days, half-life, to go to the type one  
3 sanitary landfills. And so we have got other waste  
4 going there, as well as just the hospital waste.

5 CHAIRMAN CERQUEIRA: Naomi and then Lou.

6 DR. ALAZRAKI: As I understand it, Ruth,  
7 the waste sites monitor on waste as it comes in. So  
8 they can usually identify the origin of the waste  
9 which set the alarm off.

10 And if they can identify the origin of the  
11 waste that set the alarm off, they can call the  
12 responsible parties and say come get it. And in  
13 general the responsible parties -- it happens very  
14 little to my knowledge in my area.

15 MR. GRAHAM: Let me clarify that in  
16 Michigan they say send the truck back. In Michigan,  
17 they just send the truck back, and once you pay for a  
18 truck going into a dump, and coming back, you don't do  
19 it twice.

20 DR. ALAZRAKI: Right.

21 MR. GRAHAM: So you get a really upset  
22 teamster driver, and you don't do it twice.

23 CHAIRMAN CERQUEIRA: That could be risky.  
24 Lou.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1           MR. WAGNER: I think the problem is a very  
2 interesting one. First of all, has anybody has any  
3 experience with them returning waste to a home? I  
4 don't think that has ever occurred, although I do know  
5 that toothbrushes and things like that --

6           MS. MCBURNEY: Diapers.

7           MR. WAGNER: Yes. Usually what happens  
8 is that from a hospital it is usually a radioactive  
9 material that has been disposed of into a baby or into  
10 a patient, and so it is legally disposed material, and  
11 then it gets into a diaper or something, and then it  
12 gets shipped out.

13           Other times it is catheters from the  
14 cardiac lab that get thrown into the normal trash for  
15 some reason because somebody was negligent about doing  
16 that, and then that gets caught. And that is actually  
17 the difference.

18           But I don't think that we should separate  
19 whether or not it is -- that under those  
20 circumstances, I really don't think as far as safety  
21 is concerned that we should really separate whether it  
22 is properly disposed of or not properly disposed of.

23           The issue is whether it is a safety  
24 problem. I have always contended that the waste  
25 itself is more of a safety problem than the

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 radioactive material that is in there most of the  
2 time.

3 The biggest concern they have is whether  
4 or not there might be a source that really is  
5 something of a concern, such as a cobalt source, or a  
6 cesium source, or something like this.

7 So it seems to me that this would be a  
8 -- I don't know, maybe a possibility for some really  
9 good grants and research to develop detectors that can  
10 separate this stuff out for these facilities. We have  
11 got the technology to do this stuff. We ought to be  
12 able to separate it out.

13 I don't know. Could it be a  
14 recommendation of the NRC? Can the NRC issue a  
15 request for proposal on the development of such  
16 detectors and things of that nature?

17 DR. VETTER: It may already exist.

18 MR. WAGNER: It may already exist then,  
19 and they should be able to automatically be able to  
20 channel out whether or not it is an acceptable or not  
21 acceptable radioactive material, and they have to  
22 recommend to the waste facilities that they start  
23 using these things.

24 CHAIRMAN CERQUEIRA: Richard, and then  
25 John, and then we will wrap up.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 DR. VETTER: There are multi-channel  
2 analyzers that would easily tell the operator what the  
3 radionuclide is.

4 MR. WAGNER: But does it automatically  
5 check it?

6 DR. VETTER: Well, yes. The same  
7 detector, and just hook it up to the multi-channel  
8 analyzer. But it is expensive.

9 CHAIRMAN CERQUEIRA: And you don't have  
10 the expertise at these sites to do that.

11 MR. WAGNER: You need equipment that would  
12 automatically do that and pick that up.

13 MR. GRAHAM: I guess I would conclude that  
14 if you can find a foundation that wants to pony up the  
15 money to do that research, fine, but if you are  
16 proposing Federal tax money being allocated to do  
17 that, I would not recommend it.

18 CHAIRMAN CERQUEIRA: All right. Well, I  
19 am not sure where else you would like us to go with  
20 this, John. I think you have heard some general  
21 comments.

22 MR. HICKEY: We just wanted to hear the  
23 general discussion.

24 DR. VETTER: I don't know if the NRC has  
25 considered any guidance to hospitals, but there are

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 things that hospitals can do. Number One is to make  
2 sure that they follow their procedures, which I think  
3 most do, but in terms of 35.75, they can instruct  
4 incontinent patients, for instance, to hold their  
5 diapers in the garage for a week or two. We do that.

6 I mean, most patients aren't incontinent,  
7 but occasionally that does occur, and so you simply  
8 have to instruct them a little differently than you do  
9 the normal patient. And I don't know if that would be  
10 useful guidance, that kind of thing. And if in fact  
11 most of this is coming from medical sources.

12 MR. WAGNER: The best solution is John's  
13 solution, because we have experienced the same thing,  
14 and once you get that expense thrown back at you, what  
15 you do is you invest money into a detector that is  
16 just before the garbage goes out to the waste  
17 facility.

18 And anything that goes by it sets off that  
19 alarm, and it gets brought right back into a storage  
20 room, and just sent for decay, and that is the best  
21 solution, and maybe that kind of a recommendation  
22 could go out to users and say there is this  
23 difficulty, and to avoid this expense, you may want to  
24 consider this.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 CHAIRMAN CERQUEIRA: I definitely put the  
2 expense that the agreement States have to bear fairly  
3 often on the offender. All right. Fred Brown wanted  
4 to make a comment to a couple of the issues that came  
5 up before.

6 MR. BROWN: Thank you, doctor. Yes, there  
7 is some good points that were raised relative to  
8 license conditions and guidance, and the NRC is using  
9 standardized guidance for license conditions.

10 And what may appear arbitrary to one may  
11 not appear arbitrary to the other any time two of us  
12 sit down and discuss the issues.

13 We are currently -- and literally  
14 yesterday, we were talking about is there a  
15 prescriptive guidance that we can get out of our  
16 instructions that will reduce the burden on you and  
17 us, and that will make us more efficient.

18 And specific ideas are always welcome.  
19 They can be provided directly to John or myself, or to  
20 the regions. And there is a lot of common ground I  
21 think going forward in that area.

22 One thing that I do want to be real clear  
23 on though is that there are things that are  
24 inappropriate for NRC employees to do, and they are  
25 taken very seriously, and if an inspector forces a

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701



1 requirement on a licensee that is inappropriate, it is  
2 contrary to the regulations, and it is contrary to our  
3 guidance, you should contact as a licensee the region  
4 or headquarters, or the Inspector General for the  
5 Nuclear Regulatory Commission.

6 And we take it very seriously, and I would  
7 hope that everyone would leave the room with that  
8 understanding. There is no question that if a  
9 specific case is provided to us that we will follow up  
10 on it.

11 MR. WILLIAMSON: If I could just ask a  
12 question of clarification. So you are telling me that  
13 there is -- and if I am hearing what you are saying,  
14 and understanding what you are saying, there is no  
15 legal basis that as the result of an enforcement  
16 action following a violation to impose additional  
17 requirements on the licensee that are not in the  
18 license or in the regulations?

19 MR. BROWN: The only legal authority for  
20 the NRC to do that is through issuing an order. A  
21 notice of violation typically requires a licensee to  
22 provide corrective actions. Those corrective actions  
23 are at the discretion of the licensee.

24 If we have concerns about the adequacy,  
25 the formal process is to deal with licensees and to

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 reach a mutual understanding. But to have an  
2 inspector tell a facility that you have to fix this as  
3 follows is not appropriate, and it is not consistent  
4 with our policy and procedures, and it will be dealt  
5 with on a case by case basis.

6 MR. WILLIAMSON: So can we be ordered as  
7 licensees to follow procedures which are not part of  
8 the rules, or existing documented licensing guidance?

9 MR. BROWN: The Commission has legal  
10 authority to issue an order to maintain public health  
11 and safety, but that is not something done by an  
12 individual inspector.

13 CHAIRMAN CERQUEIRA: Richard.

14 DR. VETTER: Just to reflect on that. Our  
15 experience with NRC has been extremely favorable over  
16 the years, and in one case we did have an inspector  
17 who cited us, and I tried to point out to him that he  
18 was wrong.

19 He was adamant that he was right, and I  
20 called his supervisor, and it was corrected very  
21 quickly.

22 CHAIRMAN CERQUEIRA: And two months later  
23 you got another inspection, right?

24 MR. WAGNER: Does our guidance filter down  
25 to the agreement States in regard to those issues?

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 MR. BROWN: There are several issues that  
2 are not covered by compatibility. Enforcement is an  
3 issue not covered by agency compatibility provisions.  
4 Some agreement States don't have formal enforcement  
5 programs, and so several things don't apply to  
6 agreement States.

7 The Inspector General world doesn't apply,  
8 and our conduct of employees may or may not apply, and  
9 enforcement does not apply.

10 MS. MCBURNEY: Under what is called the  
11 IMPAC review process, whereby the regions of NRC and  
12 the agreement States are reviewed on a periodic basis,  
13 some of the things that they look at are the  
14 enforcement, and how inspectors are conducted, and  
15 what sort of enforcement procedures are taking place.

16 And just coming from an agreement State,  
17 I would reiterate that an individual inspector cannot  
18 order someone to do that. If a facilitator is seeing  
19 that a specific licensing person is making undue  
20 requirements by unique licensing conditions -- we have  
21 a set of standard licensing conditions that are used  
22 that are very similar to NRC's.

23 But if you see that someone is putting  
24 that on the upper management would like to know about  
25 that, because we want more uniformity in licensing and

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 I was not aware of that situation. That is some of my  
2 people that you are talking about.

3 DR. VETTER: One last comment. I just  
4 wanted to say that I personally appreciate, and I am  
5 sure the entire committee appreciates, your invitation  
6 and openness to make suggestions about removing  
7 prescriptiveness in the regulations. Thank you.

8 MR. BROWN: And guidance especially.  
9 Guidance is more easily responded to than regulation,  
10 but I think I speak for John, and I hope that I speak  
11 for John in saying that we would certainly welcome  
12 both types of feedback.

13 DR. NAG: Under your new items, I had just  
14 one question basically.

15 MR. BROWN: Sure.

16 DR. NAG: More and more States are  
17 becoming agreement States. You know, once more than  
18 90 percent are agreement States, how would the NRC and  
19 the ACMUI be supported? Do we get anything back from  
20 the States? Because from what I understand, ACMUI and  
21 the NRC are supported by the licensing monies of the  
22 institutions.

23 MR. HICKEY: And fines.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 DR. NAG: If they go back to the States,  
2 do the States give something back to us for helping  
3 them do overall guidance and so forth?

4 CHAIRMAN CERQUEIRA: I have no idea. I  
5 defer to John on that.

6 MR. HICKEY: Well, I think I can answer  
7 that more generally. Right now the NRC funds the  
8 ACMUI. The States don't give the NRC money for  
9 anything, and as it should be.

10 And one of the things that we are looking  
11 at as a generic effort -- and I don't recall whether  
12 there was a report to the ACMUI in the last meeting,  
13 but we are looking at the impact of increases in a  
14 number of agreement States, and how that is going to  
15 impact NRC's role.

16 And that would be one of the things that  
17 we would have to look at, is whether the ACMUI should  
18 be more a committee that reports to the aggregate of  
19 NRC, and the agreement States, and their funding  
20 alternatives.

21 DR. NAG: Does the NRC get any funding  
22 directly from the government other than the  
23 institutions themselves?

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 MR. WILLIAMSON: Any general revenues come  
2 from the Federal Government to support NRC's oversight  
3 operations, independent of licensing fees.

4 CHAIRMAN CERQUEIRA: Do you pay your own  
5 way or are you subsidized?

6 MR. HICKEY: No. I understand that all of  
7 our money is recovered by licensees. However, we will  
8 still have reactor licensee fees. There are some  
9 charges that are moved because they are viewed as a  
10 general Federal interest, and like some universities  
11 are exempt from certain fees, and the reactors cover  
12 those fees.

13 So there are alternatives to getting the  
14 funding other than from the hospitals for this  
15 committee.

16 DR. NAG: Yes, but at this point thinking  
17 ahead, is this the time to ask the government or the  
18 Congress to appropriate some funding like from now?  
19 I mean, we could think ahead.

20 MR. WILLIAMSON: I think the ACMUI is a  
21 tiny, tiny, tiny percent.

22 DR. NAG: I am talking about the whole NRC  
23 and not just ACMUI.

24 MR. WILLIAMSON: Well, as more and more  
25 States become agreement States, where does the funding

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1       come to support this part of NRC. You shouldn't  
2       single out the ACMUI as sort of a tiny little bit of  
3       this. I think it should be structured in the way that  
4       is most effective.

5               CHAIRMAN CERQUEIRA: Exactly. But that is  
6       sort of a broader issue that really kind of exceeds  
7       the expertise of this committee, which is the medical  
8       use of isotopes. So I vote that we go for the break  
9       here, and everybody be back at 3:15, and we will try  
10      and get done by 4:00.

11             (Whereupon, meeting was recessed at 2:58  
12      p.m., and was resumed at 3:15 p.m.)

13             CHAIRMAN CERQUEIRA: All right. The first  
14      item of business is a visit from Mr. Don Cool, Dr. Don  
15      Cool, who is back, and he made one presentation, but  
16      now he has got to make another. Don.

17             DR. COOL: Thank you. This morning when  
18      I was here, before we started the meeting, and it  
19      seems like a long time ago because several other  
20      interesting things have happened upstairs of course in  
21      the meantime.

22             But before we started the meeting, John  
23      Graham and I were talking, and he had this peculiar  
24      smile on his face. And he was making very strange  
25      sort of noises about how this was his last meeting,

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 and how much he was going to enjoy it, and about  
2 whether there was any implication of the fact that  
3 this time he was now seated next to Dr. Cerqueira,  
4 either to be kept in line or otherwise.

5 And in the back of my mind as he is saying  
6 all these things, I am thinking something is terribly  
7 wrong here, because either I have gotten more  
8 forgetful than I recognize that I have been getting,  
9 or there has been some glitch in the process, because  
10 we always try to do some recognition and thanks to  
11 people who are rolling off the committee.

12 And no one had told me that dear John  
13 Graham was going off of the committee, and so I am  
14 going he has got to be pulling my leg, but I will just  
15 play along with this for some period of time.

16 And then we started the meeting, and had  
17 recognition of Dr. Naomi Alazraki. Well, a little bit  
18 later one of my staff people comes running into my  
19 office upstairs between meetings and says it true.

20 But in good true form we have scrambled  
21 around a little bit, and having validated that in fact  
22 John Graham is not pulling my leg, and that in fact  
23 this truly is apparently, unless of course we call a  
24 special session, and be careful.

25 MR. WAGNER: Hey, I'm here.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701



1 DR. COOL: You see what happens. And so  
2 I do want to take another opportunity both to  
3 apologize to John that I believed that you were  
4 pulling my leg for a good portion of the morning.

5 And to thank you for all of the efforts  
6 that you have given us, and that we do very, very much  
7 appreciate, and we also wish you the best. We know  
8 where we are, and we can still find you, and we have  
9 been known to do that.

10 And we do in fact have a certificate that  
11 I would like to give you. I will also go ahead and  
12 admit on the public record that because Chairman  
13 Meserve is not in D.C., that we will have to pull it  
14 back so that we can get the proper signature affixed  
15 to the otherwise regularly printed materials in order  
16 for this to finally become a complete and legal  
17 document. But special recognition to John Graham and  
18 much thanks for his time with the ACMUI.

19 (Applause.)

20 MR. GRAHAM: I just told Dr. Nag that you  
21 wanted to make sure that I paid all my library fines  
22 before you really sign and send that document.

23 CHAIRMAN CERQUEIRA: While Angela is  
24 coming up, I would like to personally say that John  
25 has been on this committee way before I got on it, and

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 he is a real clear thinker who really gets to the  
2 issues.

3 And we are really going to miss his  
4 ability to take a lot of the discussion and to come up  
5 with an appropriate motion. So he has been a very,  
6 very effective member of the committee, and I would  
7 like to personally thank him for all of his help.

8 The next couple of items will take very  
9 little time, and the first one is ACMUI interactions  
10 with staff, self-evaluation criteria for the ACMUI.  
11 And open discussion for the next meeting dates and  
12 agenda topics, and then I am supposed to summarize the  
13 meeting, which this time will not be as hard as it has  
14 been in the past.

15 And while we are waiting for Angela, the  
16 first thing is really the interactions with staff, and  
17 we really do need her. If we go to the next tab, it  
18 is ACMUI self-evaluation criteria, and this is  
19 something that we are supposed to do on a periodic  
20 basis to make certain that we are still meeting the  
21 needs of the NRC, and that we are squandering their  
22 money foolishly on lavish parties, and to come up with  
23 other ways that the NRC can support the efforts.

24 Maybe we could go through and look at  
25 these questions and see if they need to be changed, in

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 terms of the self-evaluation criteria. Does the staff  
2 and the ACMUI interact in such a manner as to  
3 satisfactorily address issues before the Committee.

4 MS. MCBURNEY: Are we just evaluating the  
5 questions or the responses?

6 CHAIRMAN CERQUEIRA: Do we have responses?  
7 Yes.

8 MS. MCBURNEY: The responses from last  
9 year's.

10 CHAIRMAN CERQUEIRA: Yes, I guess we are  
11 supposed to do it. It looks like we met the self-  
12 evaluation criteria.

13 MR. WILLIAMSON: I think the communication  
14 is quite good, and they have been I think improving on  
15 their feedback and giving us follow-up of specific  
16 recommendations.

17 And maybe we ought to consider when we  
18 really have a concern about something to make sure in  
19 the future that we always put it in the form of an  
20 action item.

21 CHAIRMAN CERQUEIRA: I think so. Again,  
22 an action item or a motion that basically can be  
23 clearly identified. I think we need to get some  
24 feedback from them as well. You know, the interaction  
25 should be both ways.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1                   We should get back some information, like  
2                   with some of the issues that we discussed today about  
3                   the board approval process. There is sort of a mine  
4                   field in a lot of ways, and I think we can give them  
5                   some useful input provided that we have the  
6                   information available that is before them. Dr. Nag.

7                   DR. NAG: When you are talking about both  
8                   ways, I am wondering can the NRC staff give some  
9                   feedback to us about whether we are doing a good job,  
10                  and whether we are giving them the information that  
11                  they want, and that would be helpful to us so we know  
12                  how or what to do, and how to prepare the next time.

13                  DR. DIAMOND: It would be along those  
14                  lines that I would like to have feedback to know how  
15                  effective we are in communicating our intents to the  
16                  Commissioners. I think a lot of time we spend trying  
17                  to provide intent and context to some of our  
18                  discussions, and I would like to know if what we are  
19                  doing is effective or not.

20                  MR. WILLIAMSON: And I think a follow-up  
21                  to that comment would be -- and which I fully agree  
22                  with -- is that we are not a commission level advisory  
23                  committee. We report to the Director, Don Cool,  
24                  basically. That is the sort of level that we report  
25                  to.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1                   And I noticed on page 4 of our bylaws or  
2                   charter, or whatever it is, that we are supposed to  
3                   have an annual briefing in front of the Commission as  
4                   a group, which says it is in the spring, and to my  
5                   knowledge we have not had that this year.

6                   CHAIRMAN CERQUEIRA: We have not had it  
7                   this year. There was some discussion earlier between  
8                   myself and staff, and since we didn't know the status  
9                   of Part 35, and there really had not been any other  
10                  issues in terms of updating, we could request that it  
11                  be done in the fall.

12                  MR. WILLIAMSON: I think we should. I  
13                  would really like to myself bring to their attention  
14                  this issue of board certification, and the importance  
15                  and difficulty of the rule text, in terms of its  
16                  practical implementation.

17                  I think it is very important and I would  
18                  urge us to make use of that expectation, because that  
19                  was put into -- you know, this was made up about five  
20                  years ago when I first joined this group.

21                  CHAIRMAN CERQUEIRA: Right.

22                  MR. WILLIAMSON: And it was basically just  
23                  because of this complaint that we were not a  
24                  commission level advisory committee that this was put  
25                  in as a sort of safeguard to make sure that there is

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 some mechanism for directly getting the Commissioner's  
2 ear.

3 DR. NAG: And if we are having a fall  
4 meeting and we are having it with the Commissioners,  
5 then I think it should be a two day meeting so that  
6 one day we have a regular meeting and one day with the  
7 Commissioners.

8 CHAIRMAN CERQUEIRA: So, John, I guess you  
9 are hearing the input and to basically for the  
10 November meeting to have a briefing to the  
11 Commissioners on some of the items that we think are  
12 important. Okay. Those are very good comments.

13 Number Two. Do the committee members  
14 clearly define issues for the staff and provide  
15 timely, useful objective information to the staff when  
16 requested. I think that the answer to this is yes.

17 I think the E-mail option works very well  
18 and I think Angela has been using that a little bit  
19 more than past staff members, but I certainly think  
20 that other members of the staff could communicate with  
21 us that way in a timely fashion.

22 I mean, a lot of the other organizations  
23 that I take part in, we even do votes over E-mail, and  
24 so I think that is something that should be utilized.  
25 Any other comments? Dr. Nag.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 DR. NAG: Yes. On that same thought of  
2 using E-mail, the other thing that I think the  
3 Commission or the NRC would think about is that it is  
4 sometimes hard to hold the principal meeting. But if  
5 we need to hold a quick meeting and we have a  
6 mechanism to hold a teleconference call, and have it  
7 in lieu of a meeting.

8 You know, sometimes you may have one item  
9 that takes one hour and we don't need to have a  
10 physical meeting for that.

11 CHAIRMAN CERQUEIRA: I think that is a  
12 good point, especially some of these ideas, in terms  
13 of a subcommittee that would be addressing specific  
14 issues. That is something that could be very easily  
15 handled in that way. John.

16 MR. GRAHAM: I would recommend that to the  
17 Office of the General Counsel. We have discussed that  
18 in the past, and the difficulty is to comply with the  
19 threshold for a public meeting of the Federal  
20 Government, and to do it over an internet forum.

21 DR. DIAMOND: So maybe that would be best  
22 confined to any subcommittee work that we might do.

23 MR. GRAHAM: Yes.

24 MR. WILLIAMSON: Even with subcommittee  
25 meetings, you can't do it. I would also say that for

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 a large group like this, with more than 5 or 6 people,  
2 I think it is pretty tough to have a productive  
3 conference call.

4 DR. DIAMOND: On that same issue, as far  
5 as efficiency, perhaps we could also go -- instead of  
6 Angela having to send us the big binder full of the  
7 minutes from each meeting, perhaps we can have an  
8 option of just accessing that on line as well, and  
9 save some trees.

10 CHAIRMAN CERQUEIRA: I think that is a  
11 good idea. We have killed quite a few trees at this  
12 meeting as well.

13 DR. DIAMOND: We did pretty good today.

14 MR. WILLIAMSON: Yes, it is quite slender.

15 MR. WAGNER: I notice that they took to  
16 heart my recommendation that the multiple slides be  
17 put on each page.

18 DR. DIAMOND: That's right.

19 CHAIRMAN CERQUEIRA: Okay. Any other  
20 comments?

21 MS. HOBSON: On the public meeting issue,  
22 in California, we handle that by actually noticing  
23 meetings and giving the public a telephone number that  
24 they can call and they can be at least listening in on  
25 the conference call.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701



1                   CHAIRMAN CERQUEIRA: That's a possibility.  
2           I am on a HFCA committee, and basically anytime that  
3           you get more than three people together, it  
4           constitutes a public meeting, and you need to have  
5           Federal Register notice and everything else.

6                   Well, I think that is something to  
7           consider. The committee is quite flexible in working  
8           with some of these issues. There are regulations that  
9           prohibit some sort or types of interactions, and we  
10          should work on that.

11                   So, Angela, maybe we can give this back to  
12          you. We kind of leaped ahead a little bit in the  
13          earlier sections.

14                   MR. WILLIAMSON: We are starting the self-  
15          evaluation.

16                   MS. WILLIAMSON: Okay.

17                   CHAIRMAN CERQUEIRA: Maybe you can go to  
18          that.

19                   MS. WILLIAMSON: Well, I will try and make  
20          this very quick. It is not that complicated. There  
21          has just been a couple of changes, and not anything  
22          monumental. But one of our recent procedural changes  
23          as you are all actually aware of is the fact that we  
24          now for the recommendations in the past, that maybe  
25          they didn't get addressed in the most prompt manner.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 Well, what we are doing now is we having  
2 the IMNS division director -- Don is answering those  
3 questions, and we are forwarding our stance on the  
4 issues that have been raised, and the recommendations  
5 that have been raised. We are forwarding those  
6 directly to you as we did before this meeting today.

7 And we would ask you that if you prefer  
8 the briefing book in advance to go over it, or you  
9 would just rather wait until you got here to get it.  
10 The good thing about seeing it in advance is that you  
11 do get the chance to read through things, and the  
12 downside though is that when things change, it is not  
13 always feasible or easy to -- we don't want to provide  
14 you with 17 revisions. So that is the downside.

15 CHAIRMAN CERQUEIRA: Jeff.

16 MR. WILLIAMSON: Yes, I have a similar  
17 problem with a large committee that I run in the AAPM.  
18 We have gone to a website based directorate, and we  
19 put all the hundreds of pages on there, and then  
20 revisions can be slipped in and out easily, and they  
21 are all in the formats so that people can download  
22 them, and print them out, or whatever they want to do.  
23 Is that a possibility, that you could put it on a  
24 secure website for us to look at as PDF documents?

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 MS. WILLIAMSON: Yes, that is a  
2 possibility. We are at the current moment developing  
3 an ACMUI website. So that is on our to do list.

4 MR. WILLIAMSON: And then people could  
5 have a range of options to access the material and  
6 what form you put it in.

7 MS. WILLIAMSON: Okay. And the travel  
8 voucher procedures, along with the professional  
9 voucher procedures. We all know that there are issues  
10 with those things. So we are going to very briefly go  
11 over those issues.

12 The thing that I would like to do a little  
13 bit differently -- and I know that it is not  
14 necessarily going to work perfectly, but what I would  
15 like to do is -- my overall vision is to not let  
16 anyone walk out with anything unless there is no way  
17 around it.

18 Because in the past it seems that the most  
19 challenging and most difficult thing to do sometimes  
20 is to get signatures. So if we can get the paperwork  
21 filled out to the extent possible before people leave,  
22 and get the paperwork signed, and just leave it, then  
23 that is going to alleviate a lot of the issues that we  
24 have of getting people paid promptly.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 Another issue that I want to point out is  
2 the Federal Government does not like to issue checks.  
3 It is going to save us both a lot of frustration if  
4 you go on ahead and fill out the direct deposit forms,  
5 and unless it is a one time only payment, the Federal  
6 Government does not want to issue you a check.

7 So please, if you have not done that, take  
8 care of that. I have passed out direct deposit forms.  
9 If you don't need to fill out the form, just ignore  
10 it. But if you do, please do that so that we can this  
11 into our payroll center and get you paid.

12 MS. MCBURNEY: If that was done in the  
13 past do we have to repeat it?

14 MS. WILLIAMSON: No, you don't have to  
15 repeat it. Regardless of the type of payment, the  
16 government does not want to give you a check for it.

17 MR. WILLIAMSON: How can we fill out the  
18 travel voucher if we don't know what all the expenses  
19 are going to be? How can we do that in advance?

20 MS. WILLIAMSON: My proposal is that you  
21 leave the paperwork here and just forward to me  
22 whatever the fees you might have had are. We don't  
23 need a receipt unless the expense is over \$75. We  
24 need the original hotel receipts, and we need the  
25 receipts for expenses over \$75.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 DR. NAG: So, \$75 for all the expenses or  
2 \$75 per expense?

3 MS. WILLIAMSON: Per expense.

4 MR. WILLIAMSON: So do you just want us to  
5 sign the complicated form that none of us know how to  
6 fill out in advance and leave it with you, and then  
7 take the simple form home with us, and then after we  
8 know what the amounts are, fill it in and send it back  
9 to you?

10 MS. WILLIAMSON: You can fax it to me.

11 MR. WILLIAMSON: So you just want us to  
12 sign the NRC Form 6041 in advance; whereas, in the  
13 past, we were filling out the work sheet and then you  
14 would send us back a filled out voucher, and we would  
15 sign that and send it back to you.

16 MS. WILLIAMSON: Right.

17 MR. WILLIAMSON: So that we are trying to  
18 eliminate that additional step?

19 MS. WILLIAMSON: Right. This is just a  
20 proposal, and it might just work out very well.

21 MR. WAGNER: On the voucher for  
22 professional services, I guess there is some  
23 confusion. My understanding is that it starts from  
24 your time of travel, and it includes your travel, as  
25 well as your time here.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 MS. WILLIAMSON: Yes, it does.

2 MR. WILLIAMSON: And isn't there a rule  
3 that if it is more than 5 or 6 hours in one day that  
4 you are supposed to charge the whole day; is that  
5 right?

6 MS. WILLIAMSON: Right. Over 6 hours, you  
7 get the full days pay. If it is less than 6 hours,  
8 then you get the hourly rate. Also on your  
9 professional voucher, there is a contract number.

10 This form that was actually filled out for  
11 you when you were brought on to the committee, it has  
12 a contract number on it, it is very helpful if you can  
13 put that number on the professional voucher.

14 (Multiple discussions off the record.)

15 CHAIRMAN CERQUEIRA: All right. Moving  
16 right along. Let's go to the self-evaluation.  
17 Angela, we had already started that, and gone through  
18 a couple of the things. What else would you like us  
19 to do with that?

20 MS. WILLIAMSON: Well, there is really  
21 -- I just revised the last one so that you basically  
22 know what you said the last time, and maybe it would  
23 help you formulate things that you would have  
24 forgotten. I don't really have a whole lot of input  
25 into the self-evaluation.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 CHAIRMAN CERQUEIRA: I guess my question  
2 is are we supposed to do another self-evaluation?

3 MS. WILLIAMSON: Yes.

4 CHAIRMAN CERQUEIRA: >From this meeting,  
5 as opposed to --

6 MS. WILLIAMSON: Yes, we are due a self-  
7 evaluation from the committee.

8 MR. WAGNER: I think it should be pointed  
9 out that --

10 MS. WILLIAMSON: There was a meeting in  
11 November.

12 MR. WAGNER: -- there was a commission  
13 briefing wasn't it?

14 MS. WILLIAMSON: No, a regular meeting.

15 MR. WAGNER: There was no spring meeting.

16 CHAIRMAN CERQUEIRA: I think there was a  
17 spring meeting actually.

18 (Multiple discussions off the record.)

19 MR. WILLIAMSON: I think to go back in  
20 time, before Barry Siegel was Chairman, where this  
21 committee was very more of a -- and so I think that  
22 the committee as a whole should be proactive and stay  
23 in the process and keep the meetings.

24 I don't think we should compress the  
25 format if we have any choice about it, because over

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 the years my observations have been that this  
2 committee has been an extremely effective instrument,  
3 at least at the level of small detail, and has had an  
4 important influence on the outcome of a number of  
5 regulatory meetings.

6 DR. NAG: Well, do we have to write  
7 something and send it to you right now or what?

8 MS. WILLIAMSON: No.

9 CHAIRMAN CERQUEIRA: Well, we have several  
10 options, but obviously we are to do a self-evaluation,  
11 which would consist of people looking at these  
12 questions and sort of addressing with several  
13 sentences at least, and what I could do if people are  
14 willing to do that and send it to me via E-mail  
15 preferably, I could then take it as an attachment and  
16 take the information and try and come up with some  
17 generalizations.

18 So if people could do that and maybe  
19 within two weeks send me written comments on their  
20 self-evaluation of the committee, answers to these 10  
21 questions, and send me comments about these specific  
22 items it would be very worthwhile.

23 The best way to do it is to send it as an  
24 E-mail attachment, and preferably in Word, and then I  
25 can paste it and bind it, and that should work.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701



1 DR. VETTER: Can I ask a question? On  
2 Item 6, do committee members bring issues, et cetera.  
3 Do members of ACMUI actually solicit from your  
4 colleagues comments or issues that they would like you  
5 to bring to the Commission?

6 CHAIRMAN CERQUEIRA: Speaking for myself  
7 and the nuclear cardiology community, I do get input  
8 from the ASNC, the American Society of Nuclear  
9 Cardiology, on some of those issues.

10 DR. VETTER: So you get that because they  
11 know that you are on the committee?

12 CHAIRMAN CERQUEIRA: Yes.

13 (Multiple discussions off the record.)

14 DR. ALAZRAKI: There is another side to  
15 this because I know that Barry Siegel, when he was on,  
16 was very careful not to be influenced by so to speak  
17 constituents, and to try not to be sort of a lobbyist  
18 type of relationship to the NRC, and I think there is  
19 a lot of merit to that thinking.

20 On the other hand, you are representing  
21 the groups, and so I think it is a tough position, and  
22 we should all be on the same page.

23 MR. WILLIAMSON: Well, I think it is very  
24 clear that we are consultants, and we are paid by  
25 virtue of our personal and professional expertise, and

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 we are supposed to speak our own minds, and to  
2 collect information. But not to represent  
3 constituents.

4 CHAIRMAN CERQUEIRA: And I think there is  
5 a fair amount of compromise that we all do with this  
6 committee and during discussions, and so I think it is  
7 important to know what our constituents represent, and  
8 we will obviously make decisions that are independent  
9 of that.

10 MS. MCBURNEY: I think it is good to know  
11 what they feel the issues are, but not necessarily to  
12 mirror the entire or what the majority of them think  
13 about particular issues, but certainly we could bring  
14 forth issues that are important, but not necessarily  
15 take a position on those as reflected by that group.

16 DR. NAG: I see myself as a consultant to  
17 the ACMUI, or to the NRC based on my professional  
18 expertise. If they want an input of the radiation  
19 oncology societies -- ASTRO or ARC -- they have sent  
20 their own particular representatives.

21 So I think I speak for myself and not  
22 necessarily for anyone else, although they may send me  
23 a message pertaining to medicine or in the oncology  
24 sense, but that's it. I don't speak for them.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 CHAIRMAN CERQUEIRA: Well, I guess getting  
2 back to the self-evaluation, should we be actively  
3 soliciting issues from our constituents.

4 DR. DIAMOND: What I do is that a week or  
5 two before the meeting, I make some calls around and  
6 what I try and do is not just contact members of the  
7 leadership of the different professional societies,  
8 but just call up a lot of people that I know that are  
9 not particularly active in the leadership just to get  
10 a sense of how they feel as practicing physicians,  
11 with the rationale that if I don't ask for their  
12 opinion, I am not going to know what they are  
13 thinking.

14 MR. WAGNER: I think I just brought up two  
15 issues today which were generated out of my  
16 communications with other RSOs, and also other  
17 communications that came to me from other sources. I  
18 don't think we have to be afraid about whether or not  
19 the issues are representative of the specific  
20 constituency.

21 I think that the discussions that go on at  
22 this table are clearly open and I think they are  
23 extremely healthy, and relatively unbiased with regard  
24 to the nature in which they are presented. They are  
25 presenting the position of the person who is assigned

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 to represent, such as myself with nuclear physicists,  
2 and Jeff with medical physicists, and we are  
3 representing our group as a whole, and trying to stand  
4 up for it, and being considerate of everybody else.  
5 I think we do a great job.

6 CHAIRMAN CERQUEIRA: All right. Have we  
7 set a date for the next meeting?

8 MR. HICKEY: We have not done that yet.

9 CHAIRMAN CERQUEIRA: Well, if we could  
10 solicit agenda items say probably after the Labor Day  
11 weekend in September, then we could have specific  
12 information for you for the agenda, and we should have  
13 a meeting in November, and at that point try to brief  
14 the Commissioners on what is going on with the  
15 Committee.

16 (Multi-discussions off the record on  
17 dates.)

18 CHAIRMAN CERQUEIRA: All right. So the  
19 24th and 25th of October tentatively.

20 MR. HICKEY: We will target that date, and  
21 we won't be able to confirm the Commission schedule  
22 this far in advance, but we can tentatively target  
23 that week and see what we can work out.

24 CHAIRMAN CERQUEIRA: So we have set the  
25 next meeting date, and the agenda items we will

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 solicit from committee members, and we will solicit in  
2 the early part of September, and plan for the meeting  
3 in the next to last week of October.

4 So I think we are down to the last item  
5 which is the summary of the meeting.

6 MR. HICKEY: Mr. Chairman, could I raise  
7 a point of order back on this self-evaluation. I know  
8 -- and I think it is in your book, but the committee  
9 did submit a self-evaluation in June, which has been  
10 less than a year.

11 So from the point of view of efficiency,  
12 if there is a perceived issue on how much effort and  
13 how productive it is going to be to do another  
14 submittal, first of all, you could do an evaluation in  
15 the context of the other evaluations, and what do you  
16 have that is already not stated in the previous  
17 evaluations.

18 Or we could check to see if anything is  
19 necessary at all. I was already hearing some comments  
20 from the committee members, but --

21 CHAIRMAN CERQUEIRA: Well, part of the  
22 reason in doing the self-evaluation is to give the  
23 Commissioners the feeling that this committee is doing  
24 something and its real goal and function is being met.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1           MR. HICKEY: And I would just draw the  
2 committee's attention to the evaluation that was  
3 already done, and there is no point in repeating  
4 things that were already stated in the previous  
5 evaluation.

6           MR. WILLIAMSON: Well, it is supposed to  
7 be done every year, and I think the reason that it is  
8 here is because June will be upon us well before the  
9 next meeting.

10          MR. HICKEY: Yes.

11          MR. WILLIAMSON: And so there needs to be  
12 feedback from the group, and I do think there are some  
13 suggestions that are in there, including -- and most  
14 of the suggestions don't really conform to the  
15 questions that were asked.

16          CHAIRMAN CERQUEIRA: Why don't we plan on  
17 getting people's input in the next two weeks then.  
18 How about by May 2nd. And so to summarize the  
19 meeting, we gave awards to Naomi and to John Graham  
20 for their service to the committee, and they both did  
21 a superb job and I hate to see them go.

22          We had the first line follow-up on items  
23 from the previous meeting. I think this time that we  
24 did get more feedback and we spent a lot of time on  
25 some of these issues, and had a lot of discussion, and

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 I think we all feel better on the feedback that we did  
2 receive.

3 And the status of the vacancies, I think  
4 what has been alluded to by Jeff, we need to be more  
5 efficient, and we had meetings where we had very few  
6 voting members.

7 And so I think that the process -- there  
8 is obviously a procedure that needs to be initiated as  
9 to the NRC staff level, and it sounds like they have  
10 a 3 person committee waiting to identify that outside  
11 Federal employee consultant and give them the input.

12 And once the notice goes out in the  
13 Federal Register, within 60 days, by the time we get  
14 all the recommendations, and by the end of the last  
15 week of that 60 day deadline, we should have a  
16 decision.

17 So, Angela, if you could maybe follow up  
18 on that, and identify the time lines, and just kind of  
19 notify either the whole committee or myself who are  
20 the NRC staff people and the outside consultants. And  
21 as to Naomi's recommendation as to her screening the  
22 recommendations for her replacement, I think we should  
23 take her up on that.

24 We heard from Cathy on the on the Part 35  
25 rulemakings and sort of identified the best case

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 scenarios of the publication in June, and  
2 implementation on January 1st, 2002. That the OMB has  
3 some issues, and that at most two months. It looks  
4 like the NRC has looked at the recommendations, and  
5 has decided that the process was too late and that  
6 same position has been sent to the OMG, and we have no  
7 idea how they will react as to that, and we will have  
8 to see.

9 Transition implementation issues, and I  
10 don't think there is much there, and the recognition  
11 of certification boards. In talking to some of the  
12 committee members during the breaks, this is an area  
13 where all of us feel uncomfortable. We feel that this  
14 is an important process and we all agree that the NRC  
15 should not be -- the practice of medicine.

16 And that we need to make certain that the  
17 eligibility requirements for some of these boards meet  
18 the requirements, and we have physicists,  
19 radiochemists, RSOs, authorized users, and we have all  
20 these different levels of radiation instances, and  
21 then all of a sudden we have gotten boards from  
22 Europe, and we have no idea what the requirements are  
23 in some of these boards, and what passing boards  
24 really means there.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701



1           So I think this is something that is going  
2           to require quite a bit of attention of the committee,  
3           and realistically if we meet that January 1st, 2002  
4           deadline, all of that will need to be in place by  
5           then, and so we don't have a lot of time.

6           We had a lot of discussion on  
7           brachytherapy procedures not covered by the FDA  
8           approval, and I think it was the uniform consensus of  
9           the committee members and the FDA representative, and  
10          the NRC, that our issue is radiation safety, and what  
11          physicians do should be -- that the NRC should really  
12          deal with radiation safety and not the practice of  
13          medicine. Jeff.

14          MR. WILLIAMSON: With all due respect, Mr.  
15          Chairman, I would like to remind you that under the  
16          sort of issue of board recognition, there was a strong  
17          recommendation to the staff that they involve  
18          appropriate ACMUI members in the discussion of  
19          implementation criteria for the current rule text for  
20          those areas where it appears that the board  
21          certification system has broken down.

22          CHAIRMAN CERQUEIRA: Thank you. The next  
23          item was the physical presence issue for the new  
24          brachytherapy procedures, and there was a lot of  
25          discussion and I think the committee in general felt

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1       that the standard is a 3 or 4 person involvement, but  
2       given some of the issues that were brought up,  
3       everybody felt trying to come up with creative ways of  
4       deciding if the alternate people be physically present  
5       should be explored.

6               And the broad licensees to utilize new  
7       brachytherapy procedures, and that the committee  
8       discussed that basically for broad scope licensees  
9       that should be left to the institutions to basically  
10      make decisions and that non-broad scope licensee sites  
11      need to go through an application process.

12             And then the rejection of medical waste by  
13      local landfills. We didn't really take a vote, but we  
14      felt that the offender or the person who was involved  
15      in disposing inappropriately radioactive material  
16      should have some financial liability for their  
17      actions, and we talked about costs associated with --

18             MR. WAGNER: Well, that is not the NRC's  
19      position to do that. The idea was that the best thing  
20      to do was to make sure that the facilities avoid from  
21      the costs from the waste companies, who will charge  
22      them for returning the waste, by installing detectors  
23      at your exit sites so that you don't accidentally ship  
24      something out, whether or not it is appropriate to  
25      ship it out or not, and that is regardless of the

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 question. The question is you should bring it back  
2 and not ship it at all.

3 MS. HOBSON: But didn't we decide to ask  
4 the NRC to send out some kind of advisory notice  
5 recommending that to --

6 MR. WAGNER: Yes, that they ought to  
7 consider the idea of notifying licensees that this is  
8 a potential solution to avoid those kinds of charges.

9 CHAIRMAN CERQUEIRA: That is pretty much  
10 the discussion. I would like to thank Angela for  
11 dealing with this travel issue, the voucher and  
12 everything else. That's great. I hope it will work,  
13 and everybody will be compensated. Lou.

14 MR. WAGNER: You did miss the fact that  
15 two issues were brought up new from the committee.

16 CHAIRMAN CERQUEIRA: Yes, I did. I  
17 apologize for that. Lou brought up two items that  
18 will be addressed by the staff. Anything else?

19 MR. HICKEY: No, I don't have any program  
20 items, but again I wanted to thank everybody for their  
21 time, and particularly for the people where this is  
22 their last meeting -- Lou Wagner, and John, I think  
23 already got away, and Dr. Alazraki, perhaps we will  
24 see you again in other contexts.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1           But we recognize that you all have busy  
2           schedules, and this is a collateral duty in addition  
3           to your full-time positions, and you have other  
4           collateral duties, and so thank you very much. It  
5           gives us a different perspective that we don't get and  
6           we don't have if we don't have physicians on the  
7           staff. So thank you very much, and thank you for  
8           bearing with us.

9           CHAIRMAN CERQUEIRA: The meeting will now  
10          be adjourned.

11                 (Whereupon, the meeting was concluded at  
12          4:13 p.m.)

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1  
2  
3  
4  
5  
6