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NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

(ACMUI)

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WEDNESDAY

APRIL 18, 2001

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ROCKVILLE, MARYLAND

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

COMMITTEE MEMBERS:

DR. MANUEL CERQUEIRA, Chairman

DR. NAOMI ALAZRAKI, Member

DR. DAVID DIAMOND, Member

MR. JOHN GRAHAM, Member

MR. TOM HEATON, Member

MS. NEKITA HOBSON, Member

MS. RUTH MCBURNEY, Member

DR. SUBIR NAG, Member

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

I-N-D-E-X

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.

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

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

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

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

In addition to the NRC staff members that will be making presentations, we have Dr. Michael Gillin, from the Medical College of Wisconsin, who will also make a statement in connection with the written statement from

the American Association of Physicists in Medicine when we talk about certification boards at 10:00 a.m.

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

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

The NRC values the opinions of the Committee very much in making our regulatory decisions. We are interested in all of the views of the committee. It is of interest to us when the views reflect an consensus of the committee, but it is also important that individual views be recorded because you represent various constituencies and stakeholders.

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

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

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

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

I would also point out that these periodic meetings are conducted in a time of change, both on the part of the committee and the NRC staff, and I would like to introduce to you Angela Williamson, which I will do in a minute.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

But we do like to take opportunities when folks are unfortunately going to have to not be part of the organization because of the rules and requirements to

provide some recognition, or appreciation and thanks for much hard work in activities.

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

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

(Laughter.)

DR. ALAZRAKI: I have always known Donald Cool.

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

DR. ALAZRAKI: Thank you.

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

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

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

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

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

So I will quickly go through the recommendations from the previous meeting. The first dealt with licensing and reporting for the therasphere modality.

The committee made a recommendation that we use the 35.400 guidance for brachytherapy. We are currently developing our final guidance, and we are going

to be very consistent with that recommendation of the committee.

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

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

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

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

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

And then the final thing that was discussed dealt with granting exemptions to training for teletherapy physicists, and the process that the

committee recommended to us is going to be adopted, where we will consult with the chair, Dr. Cerqueira, directly.

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

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

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

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

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

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

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

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

We were never sure what happened to the recommendations and so I would commend the staff. This is an outstanding summary coming back, and this is the first time that I have seen it. So, thank you.

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

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

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

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

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

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

MS. WILLIAMSON: Okay. We have a couple of vacancies, or actually one is an actual vacancy, and one is a vacancy after this meeting. The one that will be the vacancy after this meeting is the Nuclear Medicine position that Dr. Alazraki is currently holding.

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

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

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

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

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

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

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

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

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

MS. WILLIAMSON: About 30 to 60 days, because we have to get permission from the Commission for the screening panel -- from one of the people that we

need to form the screening panel, which is an outside Federal employee.

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

CHAIRMAN CERQUEIRA: But could any of that -- I mean, we are obviously going to wait for the publication and submission of applicants, but is there anything that could be done to sort of shorten the process of that appointment? Can that be made independent of the submission of nominations?

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

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

CHAIRMAN CERQUEIRA: Right. Now, they will be sent in, but they you have 60 days, and then the

Commissioners I guess have to appoint a committee. Now, is the committee the ACMUI or is it the --

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

CHAIRMAN CERQUEIRA: Of NRC staff people?

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

CHAIRMAN CERQUEIRA: Okay. So I guess the question I was asking is why couldn't that be done ahead of time in anticipation and in 60 days all of the applicants will be in so that at the 60 day time point, we could begin the process?

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

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

CHAIRMAN CERQUEIRA: I guess what the committee is recommending is that that process be

initiated so that at the end of the 60 days we would already have that group formed.

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

But it can be a bit of a logistical challenge to find that person, to mesh the schedules, and that sort of thing. It is just logistics, but we don't literally wait until the 60th day before we even begin the process of finding the other person that we need to form the panel.

CHAIRMAN CERQUEIRA: Mr. Wagner.

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

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

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

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

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

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

CHAIRMAN CERQUEIRA: Good. Okay.

MR. WILLIAMSON: Should we make a formal recommendation?

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

MR. WILLIAMSON: Yes. I would move that the ACMUI recommend to the commission that the procedure for recruiting and appointing ACMUI members begin as soon as

the vacancy becomes known, and not at the time of the actual vacancy.

CHAIRMAN CERQUEIRA: Are there any seconds on that?

DR. DIAMOND: I would second that, Jeff.

CHAIRMAN CERQUEIRA: And any discussion? Mr. Graham.

MR. GRAHAM: Just a point of clarification, because we did discuss this at two meetings back, and my understanding is that my appointment expires in October, and you are going to hear about the recruitment of my replacement today.

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

CHAIRMAN CERQUEIRA: Any further discussion?

(No audible response.)

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

(A chorus of ayes.)

CHAIRMAN CERQUEIRA: Opposed?

(No audible response.)

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

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

And what we have done towards that end is that we have already forwarded our papers up to the commission, and we have already forwarded a paper up to a point of the screening panel member, and you will be happy to know that even though my last bullet says awaiting commission approval of screening panel candidate, we have that person already approved.

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

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

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

For Dr. Alazraki's position, we just got a notice that the Federal Register notice will be published soon. So I mis-spoke on that. But it is the

Medical Physics and Health Care Administrator screening panels that will be formed in May.

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

MS. WILLIAMSON: Well, not really, because the screening panel always consists of an outside Federal employee that is skilled in the vacancy to be filled.

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

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

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

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

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

MS. WILLIAMSON: But we have to do it formally. We have to solicit or we have to contact people and do it through formal channels. We can't just say, okay, definitely you will be the one to sit on the screening panel.

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

MS. WILLIAMSON: yes.

DR. ALAZRAKI: Which I am.

CHAIRMAN CERQUEIRA: Which she is.

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

DR. ALAZRAKI: That's right.

MS. WILLIAMSON: Okay. Thank you.

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

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

MS. HANEY: Good morning. Thank you. It is rather interesting to be on this side of the table than back in the audience now. I am going to talk to you a little bit about where we are on Part 35 rule making as a whole, and also talk about the petition, the status of the petition that the Society of Nuclear Medicine and the American College of Nuclear Physicians set in.

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

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

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

All right. As far as where we are on Part 35 right now, when I last spoke with you, I told you that

the next step was to get the package to the Office of Management and Budget to get their approval on the record in keeping in reporting requirements.

That package did go to OMB the week of March 12th, and it is currently under review by OMB, and by March 16th, NRC issued a Federal Register notice just indicating that the document was with OMB, and if any individuals had any comments that they could provide OMB.

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

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

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

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

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

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

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

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

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

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

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

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

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

MR. WAGNER: Thank you.

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

(Brief Pause.)

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

And in-part it asked us to revoke all of Part 35, except for specifically identified requirements. Most of those had to do with training and experience, and also a requirement for an exam. And in the information

that you were provided it goes into a more detailed analysis of what they asked for. We did look --

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

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

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

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

And also the petition did not provide any new significant information. I'm sorry, I've had this cold for a week, and so I am actually better than what I was.

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

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

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

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

The words that you see on the view graph really comes -- well, comes straight from the staff requirements memorandum that we received. And the key

here is to realize that this reporting requirement would cover releases that were in accordance with Part 35, as well as those that were not in accordance with Part 35.

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

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

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

And then this would cause the licensee to take some type of action based on that. However, in line with all of that, we are not changing our position that we expect the licensee to follow up and enforce patient's compliance with the licensee's instructions.

And that is a very key thing, and we are going to work these two statements into the statements of

consideration for the rule. At the last meeting, when we did discuss this, and it was given maybe -- oh, I think we have 5 or 10 minutes to discuss it, we had talked about how ACMUI had made a recommendation.

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

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

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

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

But if for the committee's purposes it chooses to kind of bounce around a little bit more,

that's fine, too. And I guess I will just turn it back to you, Dr. Cerqueira, and you can -- maybe I can get all the questions on the same.

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

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

CHAIRMAN CERQUEIRA: Dr. Wagner.

MR. WAGNER: Well, I think there are two things right off the bat that I can think of that have to be considered. The first is the fact that if someone does receive more than 5 rems, then I fully sympathize with the idea that we ought to know the information, and we ought to know what generated that, and the causes that surrounded that.

The purpose of gaining and obtaining that information is to find out how prevalent that may be, and whether or not there is an issue that should be addressed

with regard to the safety of the public, and I think that is a very important issue.

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

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

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

And I think that is a concern that we all share with regard to that kind of publicity. So I think that these are the two sides that we have to look at, and that would be my issue.

CHAIRMAN CERQUEIRA: Okay. Dr. Williamson.

MR. WILLIAMSON: Well, I echo everything that Lou mentioned, but there is another concern, too, that occurs to me. And that is the fact, I think, that this rule would place the provider of care in a position to have to act upon what is essentially hearsay evidence

that the institution would become responsible for, and in a sense, for investigating this incident and acquiring information to build a case of yes or no, this happened.

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

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

And I think that this would put institutions into a real dilemma of do we report to NRC based upon this sort of hearsay, very circumstantial kind of evidence that this may have happened, and subject a patient to this kind of intrusive investigation, thereby interfering with the patient-physician relationship.

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

CHAIRMAN CERQUEIRA: So, Cathy, I guess if it is intrusive, and there is a question of anonymity for

the institution, did the commissioners deal with these specific issues, and what was their response?

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

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

MS. HANEY: Well, let me answer, too, that if we were -- that besides those two things, if we put this into effect, do you think that the licensees would be less reluctant or less willing to release patients under 35-75 when they could under normal practice?

CHAIRMAN CERQUEIRA: Dr. Nag.

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

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

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

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

CHAIRMAN CERQUEIRA: Okay. Ruth, and then Naomi.

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

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

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

CHAIRMAN CERQUEIRA: Okay. Naomi.

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

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

So the only thing that is reasonable is what I think has been specified, are the directions that the provider must give to the patient in terms of the precautionary measures that are reasonable.

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

CHAIRMAN CERQUEIRA: Richard.

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

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

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

CHAIRMAN CERQUEIRA: So, Cathy, your last question of what are the number of reports expected per year from your estimates, it has been what, one in how many years?

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

And we need to use a number in that reg analysis, and that question is there because if you collectively from having talked and knowing what goes on in the world, know of maybe some instances where this is happening, and people are not telling us, or it is not

reaching the 500 rem -- millirem limit, or whatever, is there a number other than one that I should be using.

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

DR. VETTER: My follow-up question or remark is I think or I wonder if we aren't directing our effort to the wrong place. That is, if we don't believe -- and we have no evidence to suggest that members of the public are receiving these kinds of doses, then that is not the issue.

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

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

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

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

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

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

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

CHAIRMAN CERQUEIRA: Sally, did you have any comments?

DR. SCHWARTZ: Actually, just that I think that the regulation has to focus on the institution, in terms of guidelines for the use of the patients, and

possibly making sure that the patients sign that acceptable criterion have been delivered to them, and sign the form.

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

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

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

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

CHAIRMAN CERQUEIRA: And so the comments that we have gotten are that it is impossible to implement, unworkable, unenforceable, and it is intrusive to the patient. It will probably provide inappropriate

publicity to the institution, and anonymity for the institution has been requested.

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

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

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

MS. HOBSON: I think most patients are totally unaware of the regulatory scheme that hey are being treated under. I don't think it would make any difference. Honestly, I don't think patients have a clue

as to the regulations that are there to protect the patient.

MS. HANEY: Okay.

CHAIRMAN CERQUEIRA: Okay. Lou.

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

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

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

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

And in that sense it would be reasonable for them to know that. The problem is getting information,

regardless of what the doses are. Let's say the patient breast-fed and was told not to. I mean, that is obviously a violation of instructions, or something of that nature.

And that could have led to an unwanted or untoward exposure, and that information would be useful. But the problem is reporting that. That's the whole problem, is that you can't keep anonymity for the patient, and you can't keep anonymity for the facility, even though the facility did nothing wrong.

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

CHAIRMAN CERQUEIRA: Jeffrey.

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

And that if they don't, they have to report it to the NRC. I mean, that's what you are asking. That clearly would also provide or be a major problem, too. It would probably frighten patients, and eliminate for

some of them the possibility of getting needed health care.

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

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

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

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

MR. WILLIAMSON: I concur with that.

CHAIRMAN CERQUEIRA: John, and then Dr. Nag.

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

the patient, a reporting of errors made in the delivery of instructions.

Those are the things under the control of the provider. That is a feedback, Lou, and you can improve the system and the process if you get feedback on those errors. Other than that, I don't think it is productive.

CHAIRMAN CERQUEIRA: Dr. Nag.

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

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

CHAIRMAN CERQUEIRA: Cathy.

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

DR. VETTER: An error in what?

MS. HANEY: Well, if we go back to the ACMUI's recommendation of the report -- let me pull it back up here for you. That was the ACMUI recommendation. Let me have an example of an error in the release of the patient, and what I am looking for is a real example that I can put into a document.

CHAIRMAN CERQUEIRA: Okay. John, and then Nekita.

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

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

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

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

MS. MCBURNEY: Right.

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

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

MS. MCBURNEY: Right.

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

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

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

CHAIRMAN CERQUEIRA: Other examples or other comments for Cathy?

(No audible response.)

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

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

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

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

MS. HANEY: Right.

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

CHAIRMAN CERQUEIRA: That's correct.

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

CHAIRMAN CERQUEIRA: That's correct.

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

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

MS. HANEY: The minutes or the summaries of these meetings and the transcripts are available to the Commissioners, and when we were doing the formal meetings before they were being read by the Commissioner's assistants.

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

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

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

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

MS. HANEY: We can --

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

MS. HANEY: Other than the mechanism of them getting a copy of the minutes, I don't know of one, but that is not to say that we can't try something.

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

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

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

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

CHAIRMAN CERQUEIRA: So I think the comments that I had was that it was intrusive to the patient and

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

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

MR. WAGNER: And no precedent.

CHAIRMAN CERQUEIRA: And no precedent.

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

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

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

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

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

DR. NAG: I second.

CHAIRMAN CERQUEIRA: Any further discussion?

(No audible response.)

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

(A chorus of ayes.)

CHAIRMAN CERQUEIRA: Any opposed?

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

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

(No audible response.)

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

MS. HANEY: Thank you.

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

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

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

CHAIRMAN CERQUEIRA: The OMB will basically -- let's say that under the best case scenario that on

May 12th, they give us an answer and it says no problems. Let's go ahead and do it.

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

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

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

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

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

CHAIRMAN CERQUEIRA: 2002.

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

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

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

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

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

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

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

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

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

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

MS. HANEY: I think from the standpoint that if they ask me a question, or us a question that we are not able to answer from the standpoint of impact, or what

does this mean, and I call you on the phone and say help, that you guys would return my call.

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

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

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

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

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

It is not something that is going to go into a black hole and we are going to drag our feet on responding, because we are very anxious to get the rule

published also. So I think worst case is two months, and so March of 2002.

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

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

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

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

I mean, we already have one working, but to start a second revision to the rule. So ideally you want to put out the perfect rule, but it doesn't work all the time, and that's why we have the process for revising the rules.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

And also informing the medical community and the members of the public at large what is going to be in the new rule, and answer their questions. One of the things that we -- well, to go in order. We are going to have our own training and workshops for our own staff, and for the agreement, because the agreement states regulate the majority of medical facilities as you know.

And we are going to accept as many invitations as we can to attend society and licensee

meetings, and that process has already started, where we explain what is in the new rule, and how we see life as different under the new rule.

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

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

We need to look at that registry process in light of the new rule, because some of the registration sheets old, and don't even reflect some of the necessarily developments in the existing Part 35, much less the new part 35.

And also they were not written with anticipation that Part 35 would give recognition to the registry. So that is an effort where we are going to be

working among our own staff and the agreement States to perhaps revise or issue guidance on the existing registrations, and also guidance for the new registrations so that they anticipate the New Part 35.

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

CHAIRMAN CERQUEIRA: David.

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

MR. HICKEY: Yes. It allows us in the community to have more flexibility in keeping up with new technologies. The way the current Part 35 is structured, it says that you can use radioactive material for teletherapy, or you can use it for cancer, or you can use a nuclide, cesium 137, for a certain cancer treatment.

You can use strontium 90 for a certain type of treatment. So it didn't allow for new uses of the radioactive material, or I shouldn't say it didn't allow. It had limited flexibility when new uses, and new nuclides, and new forms came along, such as using -- we

now have, for example, intravascular brachytherapy work in liquid gas and sealed sources in that area.

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

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

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

CHAIRMAN CERQUEIRA: All right. I would like to reconvene the committee, and we will start with the first item on the agenda, which is the Recognition of Certification Boards, which will be presented by Bob Ayres from the NRC.

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

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

CHAIRMAN CERQUEIRA: Okay.

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

These were the boards that we discussed with you at the last committee meeting, just to remind you of what we did cover. Certainly I am willing to entertain any questions at the end of both of our presentations on any of the previous issues that we did talk about.

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

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

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

The American Board of Radiology submitted their formal letter to us and listing those modalities which they were seeking recognition, and those were in diagnostic radiology in 35.190, 290, and 390, except for one of the special modalities listed under (g)(2) under 390.

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

And in radiological physics, they asked for the radiological physicist to be recognized both as RSOs

and as Medical Physicists under 35.50, and 35.51, respectively.

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

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

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

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

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

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

The answer is, yes, provided -- and there is really a question here of whether the board requirements meet this, but they have in that three year training at least one year of this training is under the supervision of an RSO, and that that RSO signs the appropriate preceptor statement certifying that one year of supervised radiation safety officer training has been received.

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

And they don't really -- and they all come in under 35.50(b), which is a more rigorous training and experience requirements that really were intended for

appointing dedicated and trained RSOs for large programs, with mobile medical disciplines being practiced.

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

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

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

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

MR. AYRES: Yes. I am simply addressing it from the perspective of board recognitions at this point. But if there is no board recognition, any individual can

come in and present the appropriate training and experience requirements, and if they satisfy those, be appointed to whatever authorization they request.

This is applicable to all of the authorized users and medical physicists, and nuclear pharmacists on the license. They have to be listed on the license obviously if they are applying for that additional authorization.

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

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

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

CHAIRMAN CERQUEIRA: Richard, perhaps you could comment. You know, as sort of the RSO

representative on the Board, is this acceptable you think from --

DR. VETTER: Well, as Mr. Ayres outlined, or at least as the way I heard it, an authorized medical physicist could be appointed an RSO for a therapy program, but not necessarily for a broad scope program.

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

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

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

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

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

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

MR. AYRES: Well, the only time a licensee would apply for an authorized medical physicist, the only requirement for having one, and therefore, they get the deemed status if you would, is for therapeutic perimeters.

MS. MCBURNEY: Right.

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

MS. MCBURNEY: That's true.

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

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

MR. AYRES: Yes.

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

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

CHAIRMAN CERQUEIRA: Lou.

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

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

MR. WAGNER: That would be good.

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

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

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

MR. AYRES: Right after our last meeting with the committee here, we got the letter from the Board of Nuclear Cardiology, and I have looked it over, and I see no problems, and it appears to meet all of our

requirements for recognition of the board diplomates under 35.290.

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

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

MR. AYRES: Yes.

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

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

DR. ALAZRAKI: I think that is dangerous.

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

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

MR. AYRES: No.

DR. NAG: Or only for nuclear cardiology?

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

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

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

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

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

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

CHAIRMAN CERQUEIRA: Richard.

DR. VETTER: Just to comment briefly on that. If a physician is qualified under 290, then they would become -- they could be approved as the RSO.

MR. AYRES: That's right.

DR. VETTER: But many nuclear cardiologists actually don't qualify under 290. They practice in

conjunction with a nuclear medicine physician as a team, and therefore they would not be qualified to do this. On if they were fully qualified under 290.

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

DR. VETTER: Right.

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

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

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

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

MS. MCBURNEY: I'm not either.

CHAIRMAN CERQUEIRA: Naomi.

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

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

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

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

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

DR. SCHWARTZ: It is mainly physics and chemistry.

MR. AYRES: It in some degree is a little bit analogous to the ABR certification of nuclear

medicine physicists, only this is not -- this is even more general.

DR. ALAZRAKI: Yes.

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

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

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

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

MR. AYRES: It doesn't appear to be from their submissions and we will certainly get back to that, but all of the ones citing nuclear medicine, and the medical physicists boards, and this board, and others, and even the American Board of Health Physics, have problems and/or questions about meeting the specific one year of dedicated experience under the supervision of an RSO in a medical program, and the corresponding preceptor statement.

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

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

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

What are the options for board recognition? Well, clearly the most favorable one is that they all

meet all the stated requirements of the rule, and are recognized and listed on our website as doing so.

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

In other words, the American Board of Medical Physics is deemed recognized for 35.400 to 35.600, except for stereotactic radiosurgery, and then they could just come in with additional training and experience if they got into gamma knife later in that facility, or moved somewhere else and shown that they filled in the remaining T&E requirements for that modality.

That is a question that the rule does not say anything about partial certifications. So we need to get an opinion on that. I don't know the answer yet.

And, of course, the last one is that they don't meet the rule requirements, and then there is no recognition.

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

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

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

CHAIRMAN CERQUEIRA: Bob, before Dr. Gillen, let me just try to get a little clarification, because we are initiating a procedure which is going to be operative once the Part 35 revision rule is approved, and so far we have had several discussions about boards. Now, have any of these boards that have submitted been notified of the actions of the NRC?

MR. AYRES: No, and for a couple of reasons. Well, I stand corrected on that. We just recently sent a letter to Dr. Hendy, who is the American Board of Radiology, and I believe he is the executive director,

and with the response that I just gave you today about the summation of hours, and the medical physics issues.

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

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

CHAIRMAN CERQUEIRA: Right. It would be important to have a plan, in terms of is there going to be a best case scenario. January 1st, 2002, the rule will go into effect, and at that point we should officially -- well, I guess we can't notify people until -- I guess one it has been published in the Federal Register, then people could be notified.

MR. AYRES: Yes.

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

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

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

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

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

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

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

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

CHAIRMAN CERQUEIRA: Right.

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

CHAIRMAN CERQUEIRA: Yes.

MR. HICKEY: I would like to suggest -- I think that your points are well taken. What our plan was to -- assuming that the rule -- applying the rule as it is at OMB now is to respond to the boards, and tell them which ones meet the requirements, and answer the questions of the boards that have questions so that they are on notice.

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

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

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

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

CHAIRMAN CERQUEIRA: Yes, Marjorie.

MS. ROTHSCHILD: I just wanted to clarify two things. The rule is at OMB for review of the paperwork aspects of it, record-keeping and reporting. So we would not expect that provisions that don't relate to that would change as a result of any OMB action, because the review is narrower than what we are talking about here.

And then the only other thing that I wanted to clarify is that there might have been an implication that the rule is effective upon publication. I don't

know if anybody directly said that, but as we recognize, there is an effective date. You know, a time period after which it would be effective.

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

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

MR. AYRES: If I gave you the impression that it was effective, my main point was that on publication it is final. So we know that we have a fixed target to work with. Also, that the -- well, I had another thought, but I forgot it. So I will keep quiet and let you all talk.

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

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

CHAIRMAN CERQUEIRA: One comment from Jeff.

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

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

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

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

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

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

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

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

MR. WILLIAMSON: And did they self-certify?

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

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

CHAIRMAN CERQUEIRA: I think that would be helpful.

MR. WILLIAMSON: This is just too sketchy.

CHAIRMAN CERQUEIRA: Yes. This sort of table -- and I don't even know what all the boards are

that are listed up there, and I think we have to be -- you know, I would ike some more detail on this provided in a way that we could give you some input.

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

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

The two that aren't listed there that are on the existing rule, because we have not established contact with them, are the two British boards by the way, just as a comment. But I think maybe we should have Dr. Gillin come up and give his presentation, and then have time for additional questions.

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

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

But in terms of the radiation safety issue, which is what the NRC is responsible for, those radiation

safety issues are similar. So do you really need to know all about treatment planning on the gamma knife, which is quite different, to be able to be a radiation safety officer?

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

CHAIRMAN CERQUEIRA: All right. If we could have Dr. Gillin. But again I think the intent of the board was to look at the risks that are involved and try to minimize the intrusiveness, but at the same time I don't want a nuclear cardiologist to be an authorized user for a facility that is using I-131, where they have not had any experience.

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

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

MR. AYRES: On the American Board of Physics, they clearly are applying an answer to Dr. Williamson's question of 35.400 and 600 authorizations.

I don't see anything on the radiopharmaceutical therapy that the board has submitted. I will be glad to go over it with you after during a break.

CHAIRMAN CERQUEIRA: All right. Dr. Gillen.

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

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

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

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

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

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

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

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

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

MR. GRAHAM: Just a brief question. Do we have this? Do we have a written document so we can make notes on this statement? That is a question to the staff. I am saying specifically verbatim that

observation. I have got the letter and I have read it, but --

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

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

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

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

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

MR. GRAHAM: Okay.

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

DR. GILLIN: Thank you. My second observation is that there is a substantial overlap between by-product materials and non-by-product material

modalities relative to radiation safety calibration and quality assurance activities.

It is my opinion that the accelerators are significantly more complex in cobalt-60 teletherapy units. Thus, a qualified medical physicist is well positioned to come in as an authorized medical physicist for teletherapy.

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

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

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

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

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

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

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

If the current understanding of the AAPM is correct, it is the opinion of the AAPM that the New Part

35 poses a long term negative public health issue by having the qualifications of a medical physicist being defined one way by professional organizations, and another way by regulatory agencies.

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

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

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

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

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

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

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

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

Possible Solution Three. Define a classification of authorized medical physicists who are authorized to manage the licensee's physics and safety commitment for selective by-product material modalities.

The current wording for the New Part 35 appears to require training and experience in all modalities, as opposed to a subset of modalities. I wish to thank the ACMUI for considering the possible concerns and solutions.

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

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

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

And so it is not an issue of coming out of the gate. There are some related ones, and his first suggestion looked like it would require a rule making. I think the grandfathering will be fairly broadly

interpreted, but that's my position, and not an official one at this point.

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

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

MR. AYRES: Public comments?

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

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

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

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

MR. AYRES: Well, I am looking at it in more of a -- well, the more narrow issue is how do we grandfather somebody that is listed as a -- and I am not saying that we don't have the answer right now, but a medical physicist who is listed as a teletherapy

physicist, and not as a medical physicist, because we really didn't have that in the old Part 35.

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

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

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

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

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

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

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

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

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

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

That sounded very similar to what Bob mentioned during his earlier discussion, where for example, the individual would be recognized for all entities, except for gamma stereotactic surgery, or accept for, or is that something that you think is a workable solution that you would be happy with as a means of making all parties satisfied without review of the rules making process?

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

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

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

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

The issues with HDR are somewhat different than someone who is using external means, and there I don't think you can extrapolate the experience directly. But I do agree that your external -- and your cobalt 60 would be very similar, and be extrapolated.

CHAIRMAN CERQUEIRA: Jeffrey.

MR. WILLIAMSON: I would just like to emphasize again the seriousness of the implications of a literal interpretation of the regulations as written, and if it partial AMP-ship is not recognized in any form

whatsoever, there isn't going to be anybody to provide services for radiation therapy literally.

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

MR. AYRES: I guess the comment here is that a lot of comments are coming about the rule language that would be passed, and unfortunately these would have been very valuable when the committee was working on this several years ago, and there was a chance to change it.

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

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

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

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

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

It doesn't prevent qualified people from becoming qualified medical physicists or radiation safety officers, but in fact it does not encourage board certification. Now, I know that is not NRC's purview to go out and try and get people certified.

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

CHAIRMAN CERQUEIRA: John.

MR. AYRES: I think our intent was to maintain what Dr. Gillin said, was that the board's established level of expertise would be acceptable, and

somehow we got a little bit amiss there. We got a disconnect.

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

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

MR. GRAHAM: Well, I need some clarification, and this may need clarification from the OGC. When we sat here and discussed this, clearly the intent was that if there were certification boards that were existing that covered the training that was reasonable and prudent for the protection of the public safety, that it was the most expeditious route for us to take to make sure that the adequate training had been covered.

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

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

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

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

The way we wrote this rule and had it set up was so that the boards could be a de facto partial certification. Am I hearing a legal interpretation from

the OGC that their reading this literally to be all-inclusive?

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

MR. GRAHAM: Why?

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

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

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

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

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

CHAIRMAN CERQUEIRA: In my having sat through all of these discussions that was clearly our intent. let's get a comment from Naomi, Cathy, and then perhaps the counsel could give us an interpretation as well.

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

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

And just as a broad guideline type of statement, what I would like to say is that it is very important that the NRC match their licensing to the

training and qualifications as exhibited by board certification.

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

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

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

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

DR. GILLIN: The AAPM does not certify.

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

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

MR. WILLIAMSON: Yes.

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

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

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

MS. HANEY: Okay.

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

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

MR. AYRES: Yes.

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

DR. GILLIN: Correct.

CHAIRMAN CERQUEIRA: Jeffrey.

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

I think the third one that he made was really important, and it really has not been mentioned much here, and that is to basically for the NRC staff to work carefully with expert consultants or volunteers from the regulated community to draft realistic guidelines for

supplementary training for somebody that is board certified, and say only has limited experience; either a radiation oncologist or a medical physicist candidate, but not specific experience with Cobalt 60 teletherapy.

I think that this is something that the NRC cannot do by itself, and it needs the scientific and clinical input of the community. So I would recommend that the NRC staff adopt a sort of subcommittee based approach similar to what we went through when we participated in the revision of the regulations, to develop realistic guidance for implementing supplementary training standards needed to implement the rule as written.

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

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

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

CHAIRMAN CERQUEIRA: So restate your motion then.

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

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

CHAIRMAN CERQUEIRA: Do we have a second on that?

DR. VETTER: I second.

CHAIRMAN CERQUEIRA: And discussion?

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

And what I would like to come back to and ask do you favor that type of an approach or do you favor the approach that I was questioning earlier, which is to simply go and have categorizations, such as recognized RSO versus some partiality, where an individual who is

never going to see a Cobalt unit in their life need not go through three days of training on Cobalt units to do it?

MR. WILLIAMSON: Well, I don't think that can happen in the 12 months or so we have to implement this regulation. Basically, what you are proposing would require the board certification organizations to basically redo their entire framework to basically offer certificates or board certification that is modality specific, and would specifically state Cobalt 60 teletherapy, or HDR, and so on.

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

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

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

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

MR. WILLIAMSON: That's right, but I think to the extent that this method can be applied, I think it falls in what I said. What I am basically saying is let's be realistic. We are going to have to live with the wording of these regulations most likely.

So I think it is important for the community to try and work with the NRC staff to develop a set of guidelines that will allow radiation medicine to continue to be practiced basically without disruption, and I don't believe that they have the resources or knowledge base to undertake this themselves.

And I don't think that these one day committee meetings allow sufficient input and discussion time, and --

DR. DIAMOND: To deal with those details, but I --

MR. WILLIAMSON: -- that a subcommittee is necessary.

CHAIRMAN CERQUEIRA: You know, when you create subcommittees, you are adding more work. I think the intent of the ACMUI all along was to take board certification as an approval mechanism. I guess I don't know enough about the -- and the issue has come up with whether teletherapy, gamma knife, or HDR, are sufficiently different in terms of the risks that you are going to need specific experience.

MR. WILLIAMSON: I was going to make other proposals to govern that, and to speak to that issue. I'm sorry to interrupt.

CHAIRMAN CERQUEIRA: Well, if there is no issue, and if the radiation oncologist and the people that are involved feel that the training in one is sufficient to extend to the other, then I don't see that as an issue.

But if there are some concerns that if you are using -- you know, if you need specific training in the one area, then it may not meet the language exactly. But, Dr. Nag.

DR. NAG: I think the staff, the NRC staff, is -- well, there are two different issues. One is the radiation risk issue, and the other is a medical issue about the use of that sub-modality. The medical issues are different between the three modalities.

But the radiation risk issues overlap, and therefore I think that for the NRC to say that we are making these rules because you have training in one, but not in the other, and therefore you cannot practice that modality, you are infringing on the medical issue.

But the risk issue at the same time, I think for the NRC's purpose, there really shouldn't be a differentiation. If you are board certified in radiation oncology, you would have the ability to practice all of those.

Now, for the medical issue, that I think is an issue for the hospital and if you have a radiological machine, you go through training that is recommended by the manufacturer.

If you have an gamma knife, even though I am board certified, I am not allowed to handle a gamma knife unless I go to through the training for the gamma knife. So that is a medical issue.

So I think from the NRC's point of view, board training or board certification should apply to all of them, and then medically if you have to use them, you have other medical issues and other medical certification that you have to go through to use that.

CHAIRMAN CERQUEIRA: I think enforcement may be an issue there. David, did you feel that the risk is

comparable between the three, and somebody who is trained in one has sufficient knowledge to deal with the risks of all three?

DR. DIAMOND: I think it would be inappropriate for an individual just with training with linex (phonetic) just to without any additional training to start overseeing a gamma knife radiosurgery program.

I think what we are focusing on here is that since only a minority of practices in the country have this technology, is there a need to require all applicants to go and proceed with that. Subir's point was, well, gee, if I am applying to be an RSO, it would make sense that the entity or the hospital would not go and support my petition if I am not qualified to do that.

But that would put the institutions perhaps in a little bit of an uncomfortable position.

CHAIRMAN CERQUEIRA: Ruth, how do you think the agreement States would deal with this issue?

MS. MCBURNEY: I think for the medical physicist, and for the authorized user, we would want to see some additional training, even if it is just what is required by the manufacturer, and we would like to see that.

MR. AYRES: You are really talking about what we do now.

MS. MCBURNEY: Right.

MR. AYRES: Which is that we have a narrower certification and then we require the specific training and experience to add the additional authorization.

MS. MCBURNEY: But for gamma knife, or the --

MR. AYRES: But that isn't what got put into the requirements for the new part 35.

CHAIRMAN CERQUEIRA: Well, if we are focusing on the issue aspects, if there is no safety issues, and again if the knowledge base is the same, then I don't see it as quite as much of an issue.

And I am still having a little bit of a problem. You know, David seems to feel that there are different risks.

MR. AYRES: I guess in summary that I think the NRC and this committee, and the stakeholders, all want to achieve the objective that you are talking about of the recognition of the boards, and then the actual implementation of the language. We seem to have a little disconnects as to that.

CHAIRMAN CERQUEIRA: We need to wrap this discussion up, but we still have a motion. Let's have several more comments for discussion and then we should either take a vote or move on.

MR. WILLIAMSON: Well, I would like to comment that I think we are confusing two issues here. One issue is basically whether board certification in a field like radiation oncology or medical radiation oncology physics is sufficient to be an independent practitioner, and is a reasonable grounds for assuming that the professional has sort of sufficient intellectual equipment and experience to be able to go and get the necessary training and experience, and read the appropriate papers, do the necessary supervised and unsupervised self-practice, to be able to deal with novel modalities or clinical situations that they have not encountered.

And I think the answer is yes, and I would -- and I think we should speak to that in a separate motion. My motion is a very -- speaks to the sort of political and regulatory reality that we have.

We have this regulation, and I think there is a very high chance that it is not going to be changed, no matter what we say. At least, soon. So I am proposing a mechanism whereby the community can influence in a positive way I think the supplementary guidelines that are going to obviously be mandated in order to meet the letter of the new law.

And I don't want to give the impression that I personally, or that the professional associations that I am involved with, are not in favor of extra training for new modalities.

Of course, we seek out the appropriate training that we need to do novel things as professionals who are -- well, as competent professionals would in any field. So that is not the issue.

So I think to try and make these supplementary guidelines as close to clinical reality in what we do now is what the intent of this is.

And to speak to the sort of more philosophical concerns, I would propose another motion which I will make when you are ready to entertain it.

CHAIRMAN CERQUEIRA: Well, we should proceed. John, you had a last comment, and then we should call a vote.

MR. GRAHAM: Jeffrey, I guess the concern that I have got with this whole subcommittee concept is that we are just introducing another layer of bureaucracy, and in which as we sit here we were desperately trying to avoid when the discussion first came up.

So let me suggest -- and you have a motion on the floor, and so it is moot, but this committee may

want to consider something to the effect that the ACMUI considers board certification as a favorable process for improving the quality of training and practice of a profession.

And for the purpose of implementation of the proposed revision of 10 CFR Part 35, it is recommended that the interpretation of the condition that the certification process includes "all" of the training and experience, is limited and/or partial authorization, as modified by the applicability, and/or requested status.

I don't think we have to change the rules. I think it is already in there as to how you interpret that.

MR. WILLIAMSON: I don't think we need to change the rules. I am talking about guidance, and so, no, that is not my motion at all.

MR. GRAHAM: I know, but I am recommending in lieu of subcommittees, that if we just send up the clarification that all is governed by the restrictive language in paragraphs (b), that we have gotten to the intent that board certification was the path of least resistance to get where we needed to be on documentation of training.

MR. WILLIAMSON: That is not allowed by the current rules and it just won't work. I was going to

make another motion about that to cover the rule text and its need to be revised.

CHAIRMAN CERQUEIRA: We need to go on. Cathy, you wanted to make a comment.

MS. HANEY: I just wanted to make a point. The Committee has used subcommittees before. It was in the early '90s when we were working on 35.75, and we also used it during the rule making on 35 in the nitty-gritty rule text, where we sat down with subcommittees, and we meant diagnostic and therapy.

And then what happens is that we work things out with the subcommittees, and then we come back to the full committee, and make the presentations, basically a briefing on what the subcommittee decided.

CHAIRMAN CERQUEIRA: Could we get sort of counsel's opinion on this, Marjorie?

MR. AYRES: I think she has left. I wouldn't --

CHAIRMAN CERQUEIRA: No, she is here.

MR. AYRES: Oh.

CHAIRMAN CERQUEIRA: I would agree with John that if we start adding subcommittees that it gets into a much more complicated process. If it is felt that there may be specific training in these modalities,

should that be handled at the local site. That would be the simplest way.

MR. AYRES: I would add that as a procedural matter of having dealt with this for a long time just quickly, that you as chairman, and your predecessors, have really used sort of a subcommittee system.

We referred the training and experience issue to you, and you sent it to the appropriate members with expertise in that area for their feedback, and of course when we get the committee's opinion in writing by e-mail or whatever, it goes into our databases as to that.

CHAIRMAN CERQUEIRA: But that goes to the complexity, which is part of what we wanted to do, which was to simplify. Marge, we have asked you to stand up. So we have to get your comments.

MS. ROTHSCHILD: I will provide my comments. I would just like to say that the issue having been raised with the staff, that I would expect the staff to use as it usually does, or always does, its best efforts to resolve this.

And that could include consulting with OGC if the staff deems it necessary. So I would expect the usual practice would be followed here.

MR. AYRES: Yes.

MR. AYRES: Jeffrey.

MR. WILLIAMSON: Okay. I think the issue that I am trying to address is the formulation of licensing guidance. The specific criteria of if you are a board certified physicist, for example, but have not been trained on cobalt 60 teletherapy, how many hours of training and experience do you need on top of an extensive base of linac experience to become an authorized medical physicist.

How many cases of HDR, and they could require 500 hours of HDR training and that would be ridiculous and impossible. So the intent of my recommendation is to basically recommend to the NRC staff that they involve the appropriate representatives on this committee -- and I mean those that specialize in the modalities in question in the detailed nitty-gritty negotiation of these supplementary criteria are.

It is not an attempt to create more complexity for you and the organization of this committee. It is basically recommending to the NRC that they need to involve representatives of the community who have the technical expertise and clinical experience to help formulate these guidelines in a way that is both workable and safeguards public safety.

So I just don't think it can be left to some imaginary local site or to you, yourself, with all due respect. So I think it is extensive off-line conversation that cannot be achieved in a short period --

CHAIRMAN CERQUEIRA: Well, why don't you restate your motion, and we should vote on it.

MR. WILLIAMSON: Okay. The ACMUI recommends to the NRC staff that they involve qualified members of the ACMUI in the detailed discussions leading to the formulation of supplementary training requirements that will allow board certified radiation oncologists and medical physicists to become authorized medical physicists and authorized users in modalities in which they lack the specific training and experience thereof.

CHAIRMAN CERQUEIRA: Okay. So a motion has been proposed and discussed. We will call for a vote. All those --

MR. GRAHAM: Well, we didn't get support of that motion, and we never took the old motion off the table.

CHAIRMAN CERQUEIRA: I just asked him to restate it. Do we want a second on that?

MR. WILLIAMSON: Okay. I withdraw the first motion and put this one on the table then.

DR. NAG: A slight modification.

CHAIRMAN CERQUEIRA: Okay. So, yes.

DR. NAG: You are saying only members of the ACMUI. For example, if we don't have members of the ACMUI who have expertise in that certain subject area, it should be members of the ACMUI or a specialist.

MR. WILLIAMSON: Okay. I think that's fair, or invited consultants.

CHAIRMAN CERQUEIRA: Okay. So do we have a second on the modified second?

DR. NAG: I second.

CHAIRMAN CERQUEIRA: Any further discussion on this? Cathy.

MS. HANEY: Just a notation that those meetings would have to be public meetings. So in the case where you said you didn't have someone with a specific specialty available, it would be in a public setting, and so the members of the public could be there, and I think that is getting at Dr. Nag's issue.

The other thing, too, is the way that Jeff has referred to supplementary information. You need to be very careful because you want all the requirements in the rule, and that is one thing that we have been preaching for the last three years; that there are going to be no de facto regulations and guidance documents.

And in my opinion the way that recommendation is worded right now, you could lead someone to believe that there is another set of criteria.

And I think what Jeff is really talking about is how the rule is implemented, versus coming up with supplementary criteria, and I think that is an important distinction for the record.

MR. WILLIAMSON: That certainly is a valid clarification.

MS. MCBURNEY: I have a question on that.

CHAIRMAN CERQUEIRA: Yes, Ruth?

MS. MCBURNEY: So there is going to be no additional guidance on how this is to be implemented?

MS. HANEY: Well, we have the new reg that is -- new reg 15.56, Volume 9, that basically tells you how to apply for a license in the medical area, and it has some model procedures in it for the different items.

But it is very clear in the document that those are strictly model procedures, and that there are no de facto regulations in there. It is one way of meeting it, that you can look to your professional organization for ways of meeting it.

So if from that standpoint, Ruth, yes, there is a guidance document. But from the standpoint of

training and experience, we have tried very hard to stay away from a breakdown of the hours.

Like, for example, people have said that you said 500 hours, and if we only do 10 classroom and 490 in the practical environment, are you going to accept that, and we have not commented on that at all.

So I do not envision us getting down to the point where we are saying X number of cases, observe one gamma stereotactic radiosurgery procedure, and you are okay; or observe two or this is the breakdown of hours, because that was one of the things that we tried to stay away from with this rule making, was to get at the prescriptive nature and leave the flexibility to the different organizations and the boards, and at the hospital level.

CHAIRMAN CERQUEIRA: I think this is a step away from that.

MS. HANEY: Well, it is not a step away because if you focus on the implementation of the rule, but if you are focusing it on the implementation for the purposes of breaking it down to case work level, then maybe that is somewhere where you don't want to go. And I don't think we are in disagreement, Jeff, are we?

MR. WILLIAMSON: Well, actually my intent if I were participating in such a discussion group with the

NRC, would be to sort of oppose such highly prescriptive measures, and try to get something that is sort of realistic and general as possible.

MR. AYRES: I would just comment that Jeff conditioned his with board certified, and we do come into you with non-board certified T&E issues.

CHAIRMAN CERQUEIRA: Right. All right. Let me call for a vote. All of those in favor of the proposed motion?

(A show of hands.)

CHAIRMAN CERQUEIRA: Okay. Eight in favor. Opposed?

MR. GRAHAM: I have to oppose this one.

CHAIRMAN CERQUEIRA: Okay. One opposition. Abstention? Okay. So we have recorded a vote. Now, this brings up a whole lot of other issues. I can see that the cardiology community would now want to come back and propose some changes for some of these things, although let's go ahead with this.

There is a lot of spin-offs. I don't know if we should basically follow through with some of these others, or we should go on to the next item, which is the brachytherapy procedures not covered by the FDA approval.

What is the wish of the committee? Do we need further discussion or clarification on this? Jeff.

MR. WILLIAMSON: I was going to suggest another motion.

CHAIRMAN CERQUEIRA: Make your motion and I will entertain whether --

MR. WILLIAMSON: All right. Whereas, the ACMUI believes that board certification in an appropriate specialty adequately prepares physicists to function safely as authorized medical physicists and radiation oncologists, the ACMUI recommends that the NRC staff undertake a rule making initiative as soon as possible to basically restore board certification as a sufficient condition for being an authorized user or authorized medical physicist.

DR. NAG: I don't think I understand what your intention is.

CHAIRMAN CERQUEIRA: Yes, and why just physicists? Why not all the others, and radiopharmacists and --

MR. WILLIAMSON: Because I am not sure that it is a problem for anybody else. If it is, I would certainly be adding them to the rule.

CHAIRMAN CERQUEIRA: Well, the clarification now has been that way. Lou.

MR. WAGNER: I don't think that is necessary, John Graham's interpretation of saying the

rule doesn't need to be changed. We don't have an opinion from the Office of General Counsel yet on the interpretation of this rule.

And furthermore what we have just said is the following. That we have not changed the rule at all. The biggest problem that is being pointed out is that if you want to be certified in teletherapy, and in stereotactic, or whatever, you need a year in each one of these.

The point is that there is a lot of overlap in the training. You don't need a year specifically in this and then a year in that, and then a year in that, because you can count what you have done in here in the training, and much of the training is an overlap.

You just need something that is supplemental to make sure that it adds up to a year for stereotactic, but it doesn't have to be a full year in it.

It just have to be that little supplemental thing, and he is just saying to use the expertise here to give advice to the NRC on how to get that. But don't go down to any more additional rule making, and don't do any of that stuff. That's all it is.

CHAIRMAN CERQUEIRA: I think I will take the Chairman's prerogative and just go on to the next issue. I would like to thank Dr. Gillin for his presentation,

and we will go on to the next item, which is Authorization for Brachytherapy Procedures Not Covered by FDA Approvals by Donna Beth Howe.

We can probably go until 12:00 on this because we don't really need an hour and 15 minutes for lunch, and if we don't cover it sufficiently, we could or we have got some time in the afternoon where we could make up for the time and continue the discussion.

MR. HICKEY: Mr. Chairman, this is John Hickey. I just wanted to clarify that in connection with this presentation there was a written document provided to the committee by LeBoeuf, Lamb, Greene and MacRae, representing the NOVOSTE Corporation, and there are people here from NOVOSTE in case there is any questions with respect to this issue.

CHAIRMAN CERQUEIRA: Thank you, John. Everybody should have the punched stabled, dated April 13th, and there was a copy of the letter wasn't there somewhere in here?

MR. HICKEY: Yes.

(Brief Pause.)

CHAIRMAN CERQUEIRA: All right. Dr. Howe is all set up with her audio-visuals here, and she will define the issue.

DR. HOWE: Actually, I was thinking we may be able to go to lunch early.

CHAIRMAN CERQUEIRA: I doubt it. I doubt it.

DR. HOWE: My topic is the authorization for brachytherapy procedures. I have got "and devices that are not covered by the FDA." But I am going to be focusing on the procedures that don't have FDA approval at this point.

And what I would like to do is kind of give up --

CHAIRMAN CERQUEIRA: If we could turn up Dr. Howe's microphone. Thank you.

DR. HOWE: I am going to be focusing on the procedures that aren't covered by an FDA approval, and what I am going to try to do is to give a little bit of an oversight, kind of a philosophical look at it.

And this is an extension of what Bob Ayres discussed at the last ACMUI meeting. So we are just going to be looking for additional comments from the ACMUI.

The issue is should brachytherapy licensing authorizations strictly follow the FDA approved indications for use. And at the last meeting, the ACMUI in general supported broader authorizations.

Dr. Diamond talked and essentially supported a more limited use that was in align with the FDA approved indications for use. But in general the other members were going more to a generally supported.

And what we are going to be doing is essentially looking at the medical policy statement, and using it. The staff is currently working on developing a policy to address this issue, and we are going to be using the medical policy statement as a basis.

And if you look at your handout, you will see what I have done is that I have minimized the medical policy statement, number one, because that one is not as appropriate to this discussion as two, which is the NRC rule of not intrudent to medical judgments affecting patients, except as necessary to provide radiation safety to workers in the general public.

But really the most significant part of the policy statement is going to be statement number three, which is that the NRC will, when justified by the risk to patients, regulate the radiation safety of patients primarily to assure the use of radionuclides is in accordance with the physician's directions.

So that is the particular policy statement that we will probably be using as a basic foundation as we develop our policy.

Well, we were kind of here before. Back in 1989, we had a petition for a rule making from the Society of Nuclear Medicine and the American College of Nuclear Physicians that said for the radiopharmaceutical drugs, we were being too restrictive.

We were enforcing the FDA package inserts for indications for use for therapeutical radiopharmaceutical use, and preparation for both diagnostic and therapeutic.

And we had an interim final rule in 1990, and if you look at the letter from the law firm, you will see a reference to 1990. That was the interim rule for radiopharmaseuticals, where we allowed physicians to direct changes in the preparation of radioactive drugs, and also allow physicians under the practice of medicine to use radioactive therapeutic drugs for other indications that weren't in the package insert.

And the basis for that was that the package inserts represent a position that the FDA makes that the drug is safe and effective when used for the indications in the package insert.

It doesn't say that the drug is not safe for any other purpose. It just says that it is safe for that purpose that they reviewed. So then in 1994, we

published the final radiopharmacy rule, and we had many lessons learned under the radiopharmacy rule.

And the one that is most appropriate to our discussion today is that NRC authorization for radioactive drugs were not going to be limited to the FDA approved uses.

And one of the things that you should notice is that the 1994 radiopharmacy rule was a radiopharmacy rule. It was not a radiopharmacy and medical device rule.

And I will give you a little bit of history now as to why we did not expand it to devices. One of the other things that we did in the radiopharmacy rule was one of the major concerns was that if we had a broader authorization, it might appear as if the NRC was giving physicians permission to do something that the FDA might not agree with.

And so to resolve this issue, we added 35.7 to the regulations that said nothing in this part relieves the licensee from complying with applicable FDA, and other State and Federal, requirements governing radioactive drugs.

Now, what it also did is that it said that the licensee is responsible for being in compliance with

applicable FDA and other State and Federal laws associated with radioactive drugs.

We did add devices at this point because there was no reason that this statement should be restricted only to drugs; because prior to this essentially what was happening was that the NRC was enforcing FDA package inserts which were not meant to necessarily be enforced in the way that we were doing it.

So we shifted the responsibility to the licensee. And what I would like to do is kind of give you a brief historical of where we were back in 1994 with devices.

You have seen that we had the radiopharmacy rule for radioactive drugs. Well, in 1994, we had essentially all of our medical devices that were being used for therapeutic uses, brachytherapy in particular, were coming through the traditional brachytherapy source and device approval sequence.

For FDA that meant a 510(k) process, and at NRC there was the -- it was the NRC sealed source and device registry, but the agreement States are also feeding their information into this registry.

And so we had those two elements very tightly tied together. NRC or the agreement State would wait for FDA to issue the 510(k), and that was the means

by which FDA allowed medical devices to be legally marketed.

And as soon as the 510(k) was issued, the agreement State or NRC would add the device to the registry. We would be working on the registry while the 510(k) process was going on.

And we are focusing primarily on today's discussion with proposed uses. Well, what was the situation with proposed uses under the 510(k)? Under the 510(k) the determination that the FDA made was whether the device was substantially equivalent.

The brachytherapy sources were substantially equivalent to sources and devices that were on the market prior to '76. So, it wasn't necessarily for them to end up with elaborate proposed uses.

A brachytherapy source was a brachytherapy source. Everybody understood that was going to be used for some form of cancer treatment. So you did not have specific indications for use.

So you had that proposed uses could be general, and in some cases where the devices were obviously similar to something that was on the market prior to the medical device rule, you might not even have the proposed use to address, because it was understood what it would be for.

So what do we have that is different today. First of all, we have got a lot of emerging type technologies and new uses that didn't exist prior to '76, and you also have a new medical device rule.

We are a long ways from 1976, and so it didn't make sense to continually say, well, this is substantially equivalent to something back in '76. So now the FDA in some cases will require clinical trials prior to 510(k) approval.

That wasn't going on very much back in the '80s and the early '90s. And you also had FDA pre-market approval, and that's where your intervascular brachytherapy devices are coming through a PMA process.

None of the other devices came through PMA. The high dose radio after loader, 510(k); the gamma knife, 510(k). So this is the first device that we have been seeing over here at the NRC that has come through the premarket approval process.

And there are some additional devices that are coming through from the FDA Humanitarian Device Exemption. Dr. Case at the last meeting talked about the theraspheres in the Yttrium 90 microspheres.

They are used for a very limited -- well, what might be considered an orphan disease. So their

approval came through the FDA Humanitarian Device Exemption.

And so we are starting to see some really very, very specific indications for use. In your handout in the book, I have just given two. One is in the radiation treatment of a neoadjuvant to surgery or transplantation in patients with unresectable hepatocellular carcinoma.

We never saw anything like that before in the 510(k) process. The in-stent restenosis of native coronary arteries. We never had those kinds of specific proposed uses.

What we had had in the past -- and I am quoting from 35.400, and the most recent brachytherapy device added to 35.400, was in 1989, when the Palladium 109 was added.

And you will see that the uses are as sealed sources in needles, and applicator cells for topical, interstitial or intercavity treatment of cancer.

You may have like the Strontium 90 I-applicator for superficial I-conditions. So you had very broadly stated --

MR. GRAHAM: I'm sorry, but you made a reference that we had this in our packet.

MS. HOWE: No, you don't have this. This is in the regulation.

MR. GRAHAM: We are all desperately whipping through pages here trying to find it.

MR. AYRES: It is 35.400.

DR. HOWE: It is 35.400. I am just going from the regulation 35.400. So as you can see, in the old 35.400, the proposed uses were stated in very broad terms, and what we are seeing that is different today is we are getting devices that are approved through the FDA process with very, very specific indications for use. And that is one of our differences now.

Now, one of the other things that is in the current 35.400, 500, and 600, which are our medical device regulations, is that you have very broadly described uses, and these sectors cover not only routine clinical use, but also research uses.

And those research uses could either be because the device itself is investigational, or because an approved device is being used for some other research purpose.

So it is important to keep in mind that we are dealing with both routine clinical use and also research use. Okay. What was our licensing approach to

some of the new devices, like the intervascular brachytherapy.

This is the first time that we were dealing with a device with a very specific proposed use. So initially when licensees came in and requested use of intervascular brachytherapy -- and in this case I am talking about the limited specific medical use licensees.

The broad scope licensees have a very, very broad authorization; medical research, and development, and treatment, diagnostic and therapeutic treatment.

So this has never been an issue for a broad scope. They have great latitude. So initially what the staff elected to do was that most of our licensees that were limited specific were coming in and asking for exactly what was on the FDA approval.

And so while we were developing an overall policy to address some of the more difficult issues, the easiest way to get these authorizations out and let the physicians start using these new devices, was to approve the uses as limited to the FDA approved indications for use.

Now, today we are looking at and evaluating the broader use authorization, something in parallel to where we were with the radiopharmacy rule where you are

allowing the practice of medicine for the new uses once you have got a legally marketed device.

And so that is currently under review, and what you -- and what we have done as a staff is that we have put out internal guidance to our licensing staff out in the regions, and that internal guidance was the limited approval based on the FDA recommended indications for use; in-stent restenosis of native coronary arteries for intervascular brachytherapy.

And now we are looking at revising that guidance and it is currently under review with the staff, and we have not gotten the new guidance out yet. Yes, Dr. Nag?

DR. NAG: Yes. I think we have to associate the laws of NRC and FDA. The laws of NRC is not to regulate the medical use, but to see to the radiation safety side.

For example, if you have a device, it may have a certain FDA approved use that is a medical use. The radiation safety consideration is if it were to be used for another reason.

And therefore that it is not the NRC's role to take and use it for (a), but not for (b). But we have to look to the radiation safety portion, and leave the medical use portion to the FDA. So I think we have to

divide the radiation safety issue from the medical issues.

DR. HOWE: I think we will still maintain a broad description of the medical use in order to get it into the right category and ensure the right training and experience.

DR. NAG: Sure, but that is the Part 35 -- well, where you say that nothing in this will -- you know, you still have to follow FDA regulations.

DR. HOWE: And I think that is the direction that we are intending to go, is to step back out of the specific FDA approval, but we still have to keep it in a category that we can deal with for radiation safety purposes.

DR. NAG: Right. I would like to remind the staff to do that wording in such a way that they don't have to change the wording every time the FDA comes up with new uses of the same device, because the radiation safety issues are going to be the same.

CHAIRMAN CERQUEIRA: Comments. Jeff?

MR. WILLIAMSON: I wanted to point out one comment. You mentioned that these were new devices, and that had not gone through the 510(k) procedure before, and that's strictly speaking certainly not true.

For example, the best cordis product is the same interstitial brachytherapy seed that has been in widespread use for malignant indications since 1970 approximately. So it is not a new product. It is sort of safety features that the issues of dose calculation, at least qualitatively speaking, are identical between the use in a malignant indication and a benign indication.

Now, of course, the FDA, because of the disease process being treated, required additional clinical trials to extend its use to that. But it does seem to me that that is sort of a medical issue, and why would you want to get into it, and not just sort of leave it to the discretion of the individual physician and FDA, and other health oriented Federal agencies?

Why take it upon yourself to enforce something that FDA is not going to enforce. For example, whether you are going to use the Novoste source for treatment of in-stent restenosis treated with a 25 millimeter balloon instead of a 20 millimeter balloon, are you going to -- well, that's the concern, and so how broadly or how narrowly are you going to restrict users to the specific clinical trial conditions under which the devices were developed. That's my question and you have heard my comment.

DR. HOWE: Yes, and I think the message I was trying to bring forth is that we are looking at the much broader use authorization and that's the direction that we are going into.

I can't speak specifically as to what it is going to be because we currently have that under review internally, but we are going to be, I believe, going to a much broader authorization than you have seen with what we initially did with our first license authorizations, and we have not gotten that internal guidance out yet.

CHAIRMAN CERQUEIRA: It sounds like she is agreeing with you essentially, Jeffrey. David, did you want to make a comment?

DR. DIAMOND: Yes, I think we can get to lunch on time because at the last meeting six months ago I was in the minority position. Six months ago, my primary concern was that of the safety to the public about having a very rapid expansion to the number of brachytherapy procedures being performed in a situation where some of these procedures may be performed at anatomic sites, where there is absolutely no data to support its safety to the public.

My second concern six months ago was that by taking such a move that we would effectively extinguish some very important clinical trials that were midstream,

because they would no longer receive the funding from the corporate entities to pursue them.

My thinking has changed since that meeting. Firstly, since our last meeting, there has been an increasingly amount of data suggesting that at least for the coronary arteries, and to a lesser extent the superficial feral artery system, that these techniques when performed by appropriately trained teams of cardiologists, radiation oncologists, medical physicists, or as the case may be by interventional radiologists, that if nothing else, they appear to be safe in these settings.

So that primary fear that I had was laid. Secondarily, as an individual who is kind of the director of a program where we are treating a very, very large number of patients, we face the constraints of how to treat individuals who are clearly in need of some type of modality, and that may not get this treatment without undue burden.

So perhaps to summarize my thinking, I would suggest that the staff of the NRC no longer instruct its stakeholders that FDA approved brachytherapy treatment devices, that the use of these devices -- excuse me.

That the staff of the NRC no longer instruct stakeholders that for FDA approved brachytherapy

treatment devices that their use be limited to the FDA labeled indications alone.

In other words, I am trying to balance my concern for treating patients and getting this technology out there with my concern of potential harm.

In other words, the patient who has had 3 or 4 in-stent restenosis involving a stent that is being graphed to a non-surgical candidate, that patient will die. That patient may die, and may die very soon unless we can try something.

We don't know clearly if it works long term, but certainly it appears safe. The safe thing could go for patients who may be at risk of losing a leg because of an SFA restenosis.

I say this with some trepidation, of course, because as soon as we go and move to this broader authorization, we could go and start having physicians, some of which have very little experience, start doing things that I would be very uncomfortable with, such as treatment of in-stent restenosis of the carotid circulation, or perhaps in-stent restenosis of the patient's tubular bacillar insufficiency.

But to try and weigh both of these things, I think we must go towards a broader use authorization. I would strongly encourage the professional societies to

recommend to their members that if individuals or institutions wish to look at these different anatomical sites, that they be done on some sort of an IRB approved registry, or at least some sort of registry which was a mechanism six months ago and still is a mechanism.

But as you can see, my thinking has changed to some extent. So I would be willing to make a motion to that extent.

CHAIRMAN CERQUEIRA: I am not sure they are asking for a motion, and I agree with the general support, is that we -- you know, that the NRC and the ACMUI are dealing with radiation safety.

There is issues about ethicacy, which is really up to the FDA to deal with.

DR. HOWE: And the practice of medicine.

CHAIRMAN CERQUEIRA: And what?

DR. HOWE: And the practice of medicine.

CHAIRMAN CERQUEIRA: And the practice of medicine, and there is also issues about reimbursement; that if something is not clearly FDA indicated, HFCA may not pay for it. But that is not an issue that we need to deal with.

So I think we are supporting of what Dr. Diamond is saying.

DR. DIAMOND: I agree with you fully. My primary concern six months ago was the potential effect on public safety, and if we are releasing a huge volume of new procedures for which there was very little safety data, if one excluded specific indications in the coronaries.

And again keeping with that same exact logic, with the data that we see emerging over the past six months, it forces me to modify my position as I iterated.

CHAIRMAN CERQUEIRA: Are there other comments? Dr. Williamson. Wagner, I'm sorry. The other physicist.

MR. WAGNER: I just wanted to go back to the medical use policy statement that I believe the NRC has adopted, which says that the NRC will when justified by risk to the patients regulate the radiation safety of patients primarily to ensure the use of radionuclides is in accordance with the physician's directions.

I think we have been down this road before, and I think the specific wording here puts us on very shaky ground. When they say to assure the use of radionuclides in accordance with the physician's directions, how do you define that?

We have been there before, and it is a big issue. It is a matter of what they think is in accordance, and what we think is in accordance. Two broadly different ideas.

I think this wording here puts us on a dangerous track again, and frankly I think it should have been simpler, and say something like to ensure that the use of radionuclides is prescribed by a physician. Something very general.

But not something that says, well, was the dose delivered at this point, and what it was meant to be, and was it off by this much, and down the same doggone road. So I worry about this medical policy statement.

CHAIRMAN CERQUEIRA: Do you want to comment?

DR. HOWE: I guess with respect to my discussion, it appears to me that in this particular medical policy statement we are looking at the fact that we are recognizing the practice of medicine, and the physician can make the determination of how they want to treat the patient.

MR. WAGNER: I appreciate that effort, but I am just saying that the wording that you have got here is now revisiting a path that we have been down before,

and where we run into problems with regard to interpretation.

CHAIRMAN CERQUEIRA: Do you have suggestions for changing the wording, Lou, that would be more acceptable?

MR. WAGNER: I have just seen this, and so it is a matter that I didn't have a lot of time to think about it.

But I would say primarily to ensure the use of radionuclides is under the direction of a physician, period. It is under the direction of a physician, and it doesn't have to be specific about it is in accordance with the physician's directions.

Well, what does that mean? Does it mean the physician doesn't want to deliver a dose to a certain point, and he wants to put that in there, et cetera? Those are his directions. Well, if it is off by a little bit, is that outside those rules?

That is the thing that I want to get away from, and to simply say that the radionuclides are delivered under a physician's prescription.

DR. HOWE: Well, for these devices, you do have to have a written directive, and all we are looking for is that the procedure is given in accordance with the written directive.

MR. WAGNER: All right. So then the issue that I come to is they are going to regulate the radiation safety of patients in accordance with this prescription again. To me, it is the same problems that we have revisited before.

I don't wish to make an issue of it right now. I just wish to bring the point up that I am afraid that we are going down the wrong road here.

CHAIRMAN CERQUEIRA: John, and then Nekita. John, do you want to go first.

MR. GRAHAM: Dr. Howe, could you just clarify in light of the 1994 rules that were established for the radiopharmaseuticals? At least the discussion that the ACMUI has had, where we generally supported broad authorizations.

Why did the NRC staff instruct its regions that individual licensees had to accept a condition that it was only to be used specifically as it was approved by the FDA? I mean, it is like what went out to the field was different than everything that got talked about at a very high broad policy level.

DR. HOWE: I think there were issues associated with devices that we had already addressed with radioactive drugs, but they had not been addressed with the medical devices yet, and so the staff wanted to

develop a policy and come up with the best possible policy.

And in the meantime not be seen as a hinderance in letting these devices be used at limited specific licensee sites.

More of our limited specific licensees were coming in and were requesting authorization to use the devices that had just been approved, and were mimicking the indications for use on the FDA approvals.

So there was a good match-up between limiting to the FDA approval and what the licensees were asking for, and that gave us time to discuss and air a lot of the policy issues that you will be seeing as we go to a broader authorization.

So I think it was done that way to expedite getting it out while larger policy issues could be discussed and resolved, and currently we are in the process of resolving those and anticipate coming out with a much broader authorization.

CHAIRMAN CERQUEIRA: Okay. Nekita and then Dr. Brinker.

MS. HOBSON: Well, just building on what Lou said, it seems to me that going back to number one in the medical use policy statement, where you state the NRC's mission is to regulate radionuclides in medicine for the

safety of workers and the general public, if you just inserted the work patients in there, then you could do away with number three totally.

Because I agree that the way that it is worded it is really going to get the NRC in really pretty deeply into a particular case, and trying to decide all the things that Lou said.

You know, was it the right amount and was it the right isotope, and was it delivered properly. And unless it affects safety, why do it.

DR. HOWE: Well, I know that the ACMUI and the NRC just revised the medical policy statement to be these four items, and so I think that is an issue that you may want to bring up for further consideration. But you have just gone through rule making to get to these.

CHAIRMAN CERQUEIRA: Jeff, and Dr. Brinker.

DR. BRINKER: First, I would like to thank the committee for allowing me to attend this meeting, and I appreciate the concerns brought up by committee members with regard to expanded use of intervascular brachytherapy.

I just have one question and one comment. The question is that the cardiology and their colleagues in therapeutic radiology are in a bit of a paranoic state because we have heard different things from different

sources pertaining to how we can treat the actual patient who shows up today or tomorrow, or yesterday, who has a recent in-stent restenosis or a longer in-stent restenosis that requires a pull back technique for certain devices.

And these patients are often the most refractory and the most critical to treat, and there is some hesitancy to treat them on what we would normally call a compassionate off-label basis because of concerns about our nuclear license.

So the first question I would have is what can we do today or tomorrow to counsel physicians involved in this every day practice; and the second question I have is once an official position is taken by the NRC, how will that be propagated down to the levels of the treating physician, since it would be wrong for industry to say it is all right, and you can do it.

It would be against FDA policy for advocating an off-label use. So there must be some other way of doing this in a responsible fashion.

DR. HOWE: With respect to compliance with FDA and off-label uses, that's going to be the responsibility of the licensee, and FDA, to make a determination of whether that's significant to them or not.

DR. BRINKER: That wasn't actually my question.

DR. HOWE: But I would refer to John Hickey.

MR. HICKEY: Yes, John Hickey. We have ways of electronically transmitting the position to our own licensing staff, and all of the agreement States who regulate most of the hospitals.

And then we also have a pool of about 30 to 50 institutions that have expressed interest in this procedure that we would notify, and we would ask the agreement States to notify their hospitals. So it can be done very quickly.

DR. BRINKER: And I appreciate that, and my first question is sort of -- well, when I get back today and have a patient with unstable angina, with in-stent restenosis and a stain graph, and who has come for his third time and has no option, what do I do?

I mean, I know what I will do, but how will I suffer the slings and arrows for doing it?

MR. HICKEY: Well, clearly the use would be to ask for an amendment to your license, and that could be done very quickly on an emergency basis.

CHAIRMAN CERQUEIRA: Not as quickly.

DR. HOWE: No. No, what we have to do as we are developing a larger policy issue, if we have

individual patient concern issues, we handle those very quickly. I defer to John Hickey again for any comments.

MR. HICKEY: Well, we have emergency authorization procedures that go into other issues, and we sometimes issue authorizations within minutes of getting a request if there is a patient that needs to be treated.

CHAIRMAN CERQUEIRA: We have Mr. Heaton, who is an FDA representative, and I would like to get his comments on some of these issues that have been discussed, in terms of when a device has been approved, and if Dr. Brinker decides this afternoon that he is going to use it independent of the radiation safety issues, what is the FDA's position?

MR. HEATON: There is really two different issues in here as far as I am concerned. One is the brachytherapy, does interventional brachytherapy, and prostate cancer is going through the 510(k) route, and that was what I was talking about mostly here in the presentation.

I don't have any real comment on that. If you are going through the intervascular route, FDA's position is that it simply states in our law that the FDA does not regulate the practice of medicine.

If you want to use something off-label, that's a practitioner's preoperative to decide how they will use an FDA's approved device. For FDA to become more involved in the whole issue is if you decide to do our own study to see if you can start doing it off-label, and then report that.

Then you need both the IRB, as well as an IDE, to start doing it. But the individual patient's treatment is up to the practitioner.

CHAIRMAN CERQUEIRA: So we have from again the NRC that they want to stay out of the practice of medicine. The FDA, also within certain limits, feels the same way. So I think we are getting some uniform consensus. John, and then David.

MR. GRAHAM: Well, I guess in summary, because I think part of it is this timing issue, and part of it is in the tradition of the NRC, you send out a fairly prescriptive limited interpretation while the policy was being debated.

But as I understand it as a lay administrator, and not as a practitioner, that there are patients that right now create an essentially legal dilemma for practitioners because they will be in violation of the NRC restrictions on their licenses if

they uses these devices beyond the FDA indication, correct?

Now, I understand that you have emergency authority to send out communiques, and so I guess I would suggest that this group may want to pass as a motion that ACMUI recommends immediate NRC acclamation of the concept of broad authorization for brachytherapy licensing, rather than restricting the licensing authorization to strictly follow the FDA approved indications for use.

MR. AYRES: Could I make a correction to one thing, Donna-Beth, and I think it is important to the example. We didn't stick completely with the FDA requirements. We didn't include the word native, and so the example that was given about the staff and the stain graph would not be in violation of our current authorizations.

DR. HOWE: Okay.

DR. DIAMOND: It is very difficult, Bob, trying to guess what the intent was in that type of language. I myself now that you said it have treated a number of people with STP graphs, because that is my interpretation. But a lot of other folks won't do it because of that paranoia.

But to answer the question of what can we do to help our patients in the immediate future, I would

support that the committee at this time address a resolution somewhat along the lines of what John has just put forward, and that we ask that the NRC staff promulgate this in a very effective fashion to all of its stakeholders, particularly the agreement States.

And that individuals or institutions that have broad scope licenses, such as Hopkins or my institution, that would allow us to immediately start doing these procedures for institutions that have a limited scope license.

They could go and modify their licenses to reflect this new language as well. So I think what you could see is if we move today a large number of centers very, very quickly and be able to provide this to their patients.

CHAIRMAN CERQUEIRA: So I interpret that as a second to John's motion; is that correct?

DR. DIAMOND: In a very loquacious way, yes.

DR. HOWE: I am just slightly confused, because your broad scope licensure already has a very broad authorization, and they are not limited to --

DR. DIAMOND: Paranoia will destroy you though as they say, and we get very concerned, or the administration and the radiation safety office gets very,

very concerned about going out there -- the practices get very concerned about medical liability issues.

So this type of affirmation would make all of us feel a lot more comfortable; and then secondarily, it will allow the limited scope holders to go and modify any licenses that they need to modify.

CHAIRMAN CERQUEIRA: A comment from John.

MR. GRAHAM: Let me just state what I am recommending as the motion that I think that Dr. Diamond is proposing to second, because it is to try and give that type of clarification of broad licensees as well.

It's that the ACMUI recommends immediate NRC affirmation of the concept of broad authorization for brachytherapy licensing, rather than restricting the licensing authorization to strictly follow the FDA approved indications for us.

So by making that statement, you are giving a level of guidance to the broad licensees as well of where the boundaries are being set. And all I think I am doing is trying to facilitate what you have been discussing is where the staff has landed on their recommended interpretation of this policy anyway.

CHAIRMAN CERQUEIRA: I think again that is a very good restatement. One more comment from Jeff, and then I think we should try to wrap it up.

MR. WILLIAMSON: Just to support this sort of issue of the sort of paranoia, I read from something from the ASTRO list server received on April 17th.

And I quote, "A representative from the Nuclear Regulatory Commission has indicated that any off-label use of intervascular brachytherapy other than FDA approved indication will be considered a mis-administration."

So I think that is what you have to counter.

CHAIRMAN CERQUEIRA: So I think you have gotten a sense from this committee that everybody is -- and even the FDA didn't feel that they are going to regulate it that tightly.

So we have a motion on the floor that has been seconded, and we have had discussion. If there is no further discussion, I call for a vote on the committee. All those in favor of the proposal?

(A show of hands.)

CHAIRMAN CERQUEIRA: Nine in favor. Opposed? Abstentions? So, one abstention from Ruth, representing the agreement States.

I think you have gotten a fairly consistent feedback from all of the people here, and again it is in line with the Part 35 revision, which is to stay out of

the practice of medicine, and really deal with radiation safety.

All right. I think we should break for lunch. We will make every effort to start at one o'clock.

(Whereupon, the advisory committee was recessed at 12:09 p.m.)

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.

It is not necessarily who needs to be here, but what skills need to be brought to the plate. On this

slide, we just try to break down some of the procedures for intervascular brachytherapy and who brings some of the critical skills and --

DR. NAG: Excuse me, but before you go forward, how did you make these determinations? How were these determinations done?

MR. STURZ: This is just kind of looking to see what the skills were and who might be the principal parties.

DR. NAG: Is that from your or from a society, or is that from a governing body?

MR. STURZ: This is just from what we have as far as the information from FDA approval. It is just up there for discussion, and it is not necessarily --

CHAIRMAN CERQUEIRA: So I guess this is an NRC attempt to identifying who is doing what.

DR. NAG: But this is not from any body or professional society?

MR. STURZ: No.

DR. NAG: There are publications on this already. There are official publications that are printed.

CHAIRMAN CERQUEIRA: There are various professional medical societies that are working together

to try and come up with some definitions of who is doing what.

MR. STURZ: This is just to show that different people are involved in different parts of the process. It is not hard and fast there. This is just an example.

In your handout that was provided in the previous meeting, it showed some background on how we got to where New Part 35 requirements to have the physical presence for high dose rate after loading device, both authorized user and the authorized medical physicist being present during initiation, and during and throughout the treatment.

So this is what we want to focus on, on who needs to be present during intervascular brachytherapy, both during initiation and throughout the whole treatment.

So right now our licensing guidance to our region says that the authorized user and the medical physicist, or RSO, needs to be present and consistent with the FDA guidance, and also the interventional cardiologist.

DR. DIAMOND: Excuse me, sir, but in the present -- if we are discussing SFAs, I would assume that

an interventional radiologist, if he or she does that, would be appropriate as well?

In other words, when you say that the physical treatment of the team, this is for intracoronary radiation. But if you are talking about the superficial feral artery system, in many cases it is the interventional radiologist doing it.

And it just depends on the training and the specifics of that institution, and whether the radiologist or the cardiologist is doing it.

MR. STURZ: Well, we understand that a cardiologist is going to be doing the procedure, and it gets down to the radiation safety, and it is the authorized user and medical physicist until such time as the cardiologist becomes an authorized user.

DR. DIAMOND: I think you missed the point. I guess what I am saying is that what you have is correct for the coronary circulation.

MR. STURZ: Yes.

DR. DIAMOND: But we also are now starting to treat the extremities, such as the feral artery, which is in your thigh essentially, and in that case depending on where you are, in some institutions it is an interventional radiologist and not a cardiologist that does the procedure, although some interventional

cardiologists of course do peripheral vascular work as well.

MR. STURZ: It would have to change, but I guess the issue is that who needs to be there for radiation safety.

CHAIRMAN CERQUEIRA: And I guess the other question that I have is it medical physicist or RSO, or do you always need to have a medical physicist present, and he could or may not be the RSO.

MR. STURZ: That's kind of what we want to discuss here today.

CHAIRMAN CERQUEIRA: Okay. So a lot of these things are going to be discussed rather than just being --

MR. STURZ: Yes.

CHAIRMAN CERQUEIRA: Okay.

MR. STURZ: So just to let you know that in the past couple of weeks we have gotten two letters in from two different medical societies, and that they endorse the approach, the team approach, that the NRC and the FDA has taken, and that it should be continued.

The American College of Radiology and the Society of Cardiac Radiology and Interventions also committed to developing a curriculum and training standards, which include clinical experience and

didactic, and they said that would take about 18 months for them to prepare and submit to the NRC for our consideration.

CHAIRMAN CERQUEIRA: Just a typographical error. That should be the American College of Cardiology on top, and not radiology. That would be a first, the two of them working together.

DR. NAG: When you have a society recommendation already there, there is the previous publication that is already there on intervascular radiation and personnel issues that have been published, and that were sent to the NRC about a year-and-a-half ago in one of the earlier meetings.

So I can give you a copy of that.

MR. STURZ: So some of the points that we just threw out for discussion and don't limit yourself to these questions, but obviously it is important to have a trained physician available at all times to respond to emergency situations that require source removal.

And I guess the question before us is does the inherent risk of high dose rate intervascular brachytherapy, whether it is manual or remote, justify both the authorized user and the authorized medical physicist to be physically present throughout the treatment.

Or can it be somebody who has been trained in the operation, but is under the supervision of the authorized user be present. If not both of them, then could it be either of the authorized users, or the authorized medical physicist.

Or can we leave the decision up to who should be physically present be the responsible authorized user; or is there something different that we can use besides physical presence or on call. These are the kinds of things that we would like to have you discuss and get some recommendations.

CHAIRMAN CERQUEIRA: Well, maybe we could just go through the questions, and there is five questions up there, and maybe we could try to address each one individually.

And I guess the answer to number one, I think you needed a trained physician.

DR. ALAZRAKI: Are we talking about under the current rules or the new rules?

MR. STURZ: Well, right now we are under the current rules, but six months from now we could be under the new rules, and so we would like to hear both.

DR. NAG: And are we only talking about intervascular brachytherapy high dose rate, or are we

talking about all intervascular, or are we talking about all high dose rates? They have different implications.

MR. STURZ: I think we are limiting it to high dose rate IVB.

DR. NAG: So intervascular, high dose rate intervascular only?

MR. STURZ: Yes.

DR. NAG: Okay.

MR. WILLIAMSON: And what is your definition of high dose rate?

MR. STURZ: It is in our guidance.

MR. AYRES: It is in your rules that you have in front of you.

CHAIRMAN CERQUEIRA: What does the ICRU stand for, Dr. Nag?

DR. NAG: The International Commission of Radiation Units.

MR. WILLIAMSON: Radiological Units and Measurements.

CHAIRMAN CERQUEIRA: Well, for point one, I think we would all agree that you need to have a physician present for any sort of intervascular procedure, because somebody has to introduce the catheter.

Does anybody feel comfortable that once the catheter is in there that a physician is no longer required?

MR. WILLIAMSON: I think the question is more focused than you are making it. Does a physician need to be there to implement the emergency response if something happens, and not take care of the patient.

CHAIRMAN CERQUEIRA: Okay. It does say source removal.

MR. WILLIAMSON: Yes, but they are not concerned about the quality of practice in interventional cardiology per se, but does somebody with specific training, whose job it is to respond to -- well, for example, the equivalent of a source detachment in HDR.

CHAIRMAN CERQUEIRA: Well, I guess as long as the catheter is still in the patient, you need a physician there.

MR. WILLIAMSON: I think that is correct, since basically in the procedure the physicist is sort of standing aside that is going to be the cardiologist or radiation oncologist, and there will be some physician that is manipulating the catheter, who will probably grab a hold of the thing and naturally be the first to respond.

And it is probably logical to saddle that person, or burden that person with the responsibility for having the additional training.

DR. NAG: I think what you need in that moment of emergency is somebody who in a split second can think in both directions, and think as a physician, and therefore be comfortable removing the catheter or removing the source wire.

And also in that split second, also has the radiation background to think of all the radiation safety aspects. So you need or there definitely has to be a physician, and it also needs to be a physician with sufficient training in radiation safety to know all of the radiation safety issues.

CHAIRMAN CERQUEIRA: Jeffrey.

MR. WILLIAMSON: Well, just as a sort of general comment, I think maybe there are two sort of axises to examine here in deciding what physical presence means.

I think one axis is time. If something does happen, how quickly does someone need to respond in order to correct it to avoid a medical event or misadministration. I think that would be the issue.

And I think there would be a big difference between the best cardias system which might have a 15 or

20 minute treatment time, and the current Novoste system, which would have a very short time.

And a radioactive stent for example, if it were deployed would obviously be a different time scale altogether, and you could imagine different kinds of products in the future.

So one issue that relates to physical proximity is how long do you have to respond. So a three minute response time does not mean that the person needs to be standing in the room. A 15 second response time means that they do. The second axis, I think, of the --

CHAIRMAN CERQUEIRA: Well, let's talk about that first one, because obviously if something happens, you need to take immediate action, and we have agreed that a physician needs to be there who is manipulating the catheter, whether it is a cardiologist, an interventional radiologist, or --

MR. WILLIAMSON: Could I finish? It really is important for me to finish my comment, because it impacts --

CHAIRMAN CERQUEIRA: Well, you were going on to the second one.

MR. WILLIAMSON: Yes, but they are related.

CHAIRMAN CERQUEIRA: Okay.

MR. WILLIAMSON: The second axis is the technical complexity of the device. Now, some devices, like the typical high dose rate and pulse dose rate remote after loading systems are fairly complicated systems, and it takes a significant level of technical skill sometimes to recognize that an emergency has occurred, and to sort of be able to respond to contain it.

And I think that is one of the major reasons for requiring a physicist to be there, for example. Now, I think these two axises could be different in intervascular brachytherapy than they are for typical high dose rates.

So one could make the case with some of these methods that maybe the manipulation of the device is sufficiently simple that you don't have to have a physicist on the front line to be able to sort of maybe pull the catheter out.

It is not rocket science to figure out that it is in the wrong place or that it has been too long. So I guess they are related in that sense. So it is technical complexity, which is the ability to recognize something has gone wrong, and then response time if something has happened.

CHAIRMAN CERQUEIRA: Richard.

DR. VETTER: You are using the word available in here, and in the background material that you gave us, you used two different terms, physically present and immediately available.

So that this is different, number one, than either of those. And physically present means within hearing distance, the distance of the normal voice; whereas, immediately available means available on an on-call basis, such as by telephone.

MR. STURZ: Would there be different situations where being available on call would be more appropriate than physical presence? I think that these are kind of some of the issues that maybe there is a need for somebody that may not be needed right there in the treatment room, but could respond within a short amount of time.

DR. VETTER: Well, for IVB brachytherapy, you need an oncologist just to be there. I mean, under the current rules; or a cardiologist, one or the other anyway. You need a physician there implementing the technique. So it is almost a moot point. There has to be someone there.

CHAIRMAN CERQUEIRA: Dr. Brinker, you had a comment?

DR. BRINKER: I think I was going to pretty much echo what you just said. I think nobody could argue with point number one that it is important for a properly trained physician to be available at all times.

And I was going to bring up the point that there are two problems that can occur with this form of therapy. The most common problem that would require an immediate response is acute ischemia due to the physical presence of the delivery system.

And that is best handled by the cardiologist changing that physical presence in some way. The other issue is a potential now deployment if you will of the source train.

And that the way that the guidelines are written now, it is the responsibility of the radiation oncologist. I think as things evolve that I would strongly suggest that there is some flexibility built into the approach that the NRC takes to allow sites to quality their properly trained physicians in an appropriate fashion, so that all three members of this very important team need not necessarily be physically throughout the entire procedure, which is what I would suggest.

But I think if you want to just look at Item number one, that's fine. The issue is properly trained

I think needs a little bit of flexibility. But you don't have to work on that right now to accept that point.

CHAIRMAN CERQUEIRA: Any other comments? Dr. Nag.

DR. NAG: I think since we are starting to make rules, I would like the rules to be done in such a way that they will be applicable not only to the methods that we are using today, but also the methods that we will be using tomorrow.

For example, today, yes, you are using a hand held uranium wire or the strontium. But tomorrow we are going to be using HDR, or whatever. I think we should make the rule broad enough so that tomorrow we don't have to reissue our rule again.

So my comment that I am going to make is with that in mind. That, one, that the personnel who are there would depend on which exact equipment is being used, because if it is a remote HDR applicator, that is quite different from, let's say, if you have something with strontium.

I think that is one important thing that you should keep in mind when you are making these rules.

CHAIRMAN CERQUEIRA: So how do we go and write rules that can guide us many years into the future when we don't know again what some of these may be?

In other words, we spent a lot of time earlier today trying to avoid nitpickingness in rules and regulations without -- in other words, that you don't identify specific systems and the details of particular techniques.

So how can we accomplish your goal without being overly prescriptive?

DR. NAG: Well, I think that is a good question. I would suggest that these treatments are only being done over a period of 3 to 15 or 20 minutes.

And therefore if even there is a high dose rate after loader, you would be 2 or 3 minutes, and if it needed a manual high dose rate after loader, it would be about 10 or 12, or 15 minutes.

So all of them are within that time frame, no matter which of the equipment we are using.

Some may be a little shorter, but some will be a little longer, but not much more than 15 or 20 minutes. So the personnel that we have I think we can do keeping that in mind; as opposed to something like stents, where it is in there permanently.

And so I am talking about the removal, only the removal system, and we have one set of rules, and for the permanently placed system, like the stent, we have a separate set of rules.

MR. STURZ: But again stents is not really the primary technique for discussion today.

DR. NAG: Right.

MR. STURZ: So again, I don't want to get too prescriptive on the details.

CHAIRMAN CERQUEIRA: Yes, this was an issue that over the last two years that we have had multiple discussions, and since we didn't have an approved system when we were trying to draft Part 35 revisions, we put this into the emerging technology category, the 35.1000.

We are getting to the point now where there are some devices that are approved, and we need to at least start to think about it, and I think that is what this discussion is going to be on. Naomi.

DR. ALAZRAKI: I think this is entirely too prescriptive a discussion, and we should be thinking more in generalities that are more appropriate I think for the NRC to be talking about for protection of personnel and of the public.

You have defined a team, and I don't think we should be saying what or how the practice of medicine should go on for this individual patient.

You have defined a team, and perhaps you want to state some of the radiation safety requirements in the sense that the team will ensure that there will be

minimal or no -- minimal to no possibility of any radioactivity leaving the intended location.

And that if that should occur, the team will be capable of responding in the appropriate timely fashion to correct the problem and so forth, you know.

But I don't think we should be talking about exactly prescriptively for each device how things are going to work.

CHAIRMAN CERQUEIRA: Jeffrey.

MR. WILLIAMSON: I was going to suggest a slightly different tactic, and it is different than what Naomi suggested, but I would say that we think what is about in 35.400 and 600, and think whether the device -- how similar or different the device is from there.

Now, for example, a full-blown single stepping source remote after loading device, there is a fairly carefully worked out scenario of who has to be there.

So I think for an intervascular treatment outside of the cardiac tree, where the patient would be treated nowadays with a conventional remote after loader, it seems to me that there is no reason whatsoever to have sort of special regulations.

It is already covered and the requirement is that a medical physicist be there all the time, and

authorized user there to start the treatment, and a properly trained physician, and not necessarily the authorized user, be there to implement certain parts of the emergency response procedure if it is necessary and leave it at that.

And I would say that some device that has a technical complexity comparable to the single stepping source remote after loader may be the same approach, and might want to be used.

Now, manual brachytherapy on the other hand, no matter how high a dose rate it is, does not require continual physical presence of the authorized user or the physicist.

It requires a physicist appropriately to be involved in calibration, and checking the calculation. It involves the authorized user to be there at the initiation of therapy, and I think the requirements should be that somebody -- and I think a physician from the sense of the discussion here, and who is properly trained to respond to an emergency condition be there if it is necessary to pull the source train out.

That certain manual would cover the best system that is now available, and we could argue or discuss where the Novoste system or sort of mini-hand held remote after loaders like that fall.

My sense would be that maybe it could be treated as an almost manual brachytherapy device. So that is another way to think about it.

DR. DIAMOND: Do you think then from our discussion that it would seem that you are fairly satisfied that there are current regulations on the books that would go and address the vast majority of these techniques; is that the sense that you are conveying?

In other words, manually loaded, or a remote after load system, there appears to be -- there are regulations that would cover these procedures to your satisfaction?

MR. WILLIAMSON: I think so, and I think they --

DR. DIAMOND: Because I think they do.

MR. WILLIAMSON: I think they allow a lot of flexibility. They are carefully thought out, taking into account both the sort of complexity axis and response time axis to reflect the standards of the community.

I don't see why a 20 minute treatment in the case of malignancy is any less dangerous or more dangerous than a 20 minute treatment in the cardiac tree for a comparable dose.

DR. DIAMOND: I agree with you. I think that the discussion is almost moot because to me high

dose brachytherapy is high dose brachytherapy, and the distinction is manual versus remote.

MR. WILLIAMSON: I think so.

DR. DIAMOND: And the regulations are there, and they work, and people are protected.

CHAIRMAN CERQUEIRA: I guess the issue with some of these hand held manual type devices is that they are emerging technology in the application, and so the discussions that we have had in the past was that they would probably need to be relooked at in the future when they were approved and considerations being made. And which I think is still under discussion.

DR. NAG: Manuel, one thing.

CHAIRMAN CERQUEIRA: Yes.

DR. NAG: I think here again as an emerging technology, we have to differentiate the two issues. One is the medical necessity and the medical applicability, and the radiation safety.

The radiation safety issue, even though this is an emerging technology, instead of using it in the esophagus, you are using it in the coronary vessel.

The medical applicability and the medical indications are different, but the radiation safety indications are exactly the same as whether you are using

the high dose rate in the coronary vessel, or in the esophagus, or in the lung.

And I agree with Jeff that the regulations offer the use of any high dose radiotherapy is already worked out in other organs, and in terms of the radiation safety issue, it is no different doing it in the heart.

So, therefore, instead of trying to make a new set of regulations, try to implement the same set of regulations and it is much easier for everybody.

CHAIRMAN CERQUEIRA: I think those are good points. We have had discussions here in the past from the cardiology community. We had Dr. Razner here last time, and we have had Dr. Warren Laskey in the future, and there was some discussion whether these things would be done emergently.

Well, you didn't have all the appropriatial elective time to do all these procedures, and there was a time element on things that you needed to initiate for treatment in a timely fashion.

And there were issues related to how many people did you need there, and what would be the training requirements. And there was some input from the cardiology community that there would be considerable delays introduced related to patient safety by having a whole team approach.

DR. DIAMOND: So, for example, we discussed it with Dr. Rasner last time that the outcome of the patient is our primary concern. However, if you follow the same logic that time is always of the primary importance, then by extension, one could do these procedures without any oversight whatsoever.

And then in that regard, then you are really starting to move in an area where there may not be an appropriate degree of oversight in my opinion.

For example, let's say that at two o'clock in the morning a person is having an acute MI, and someone wants to use vascular brachytherapy. I personally think it would be extremely dangerous to the public safety to have these procedures being done by a cardiologist and a cardiologist alone in the middle of the night.

I just can't even begin to fathom that type of thing. So I fully understand that particular point of urgency, but we can't go and sacrifice that time urgency for the primary case of safety and oversight.

CHAIRMAN CERQUEIRA: Well, I don't think that was the point, but Dr. Brinker, you had a comment?

DR. BRINKER: Thanks. This is obviously a very complex issue and technology is evolving such that many of the classical relative roles will change.

And what I would propose is to think about flexibility now so that when one can adjust a bit to the future. But I would like Dave to take away the idea that cardiologists would consider doing this all by himself in the middle of the night for an emergency, because I don't think that is appropriate.

On the other hand, I can tell you a true problem as a practicing cardiologist with an approved device, and that is that many, many institutions do not have the radiation oncology manpower to give not 24-7, but five day a week, 8 hour coverage.

And I have the utmost respect for my own radiation oncologist at Hopkins, who are underpowered right now, and who are wonderful people, and who have worked diligently with us, the cardiologists, in doing the clinical trials of these devices.

But right now they can only give us a half-a-day twice a week for radiation oncology coverage, and they are going to work very hard to improve that.

But this is not unique to Hopkins. It is not an isolated situation. It is something that I hear a lot, and what I would like to at least have people thinking about is that there are many ways that one could approach this.

But the way that the Europeans seem to have taken is to maintain the concept of the team approach, but have taken the position in many places in Europe that two members of the team are adequate, with the third member being available, but not physically present necessarily.

At least the concept of flexibility, and that is, at any one center, if all three members of the team agree that two members of the team are properly equipped to do these procedures, being physically present, and the other one being remotely present -- not at home in bed, but in another area of the hospital perhaps -- that that may be acceptable.

I don't think that we should reject it out of hand, and the more flexibility that we build into the system, I think the better it is going to be for the patients, which is really the primary issue.

And I will give you another example. Two weeks ago, I had a patient admitted with unstable angina on Saturday. He had in-stent restenosis and we knew that. This is his third recurrence.

And I get back up only on Tuesdays and Fridays, a half-a-day each. And by Monday, he was having ongoing rest pain, and I had to take him to the lab, and I just opened up his artery a little bit with a balloon,

and then brought him back the next day totally off-label compassionately, and finished the angioplasty, and then on that Tuesday did radiation therapy with the full team being present.

Now, this is not shown to be an effective methodology, but I felt that I had no choice for that patient, and I think that around the country that there are a million angioplastys a year, and 80 plus percent of them get stents.

And in-stent restenosis makes up about 20 percent of the patients we do now. We are talking about huge numbers.

And if you had a stent and you came in and somebody said, well, we really can't do you here until the next day or two days down the line, you will just have to make do with what you have, it is an uncomfortable thing that I think is not necessitated by true safety concerns.

I think in the proper environment, with all three people, entities working together, these things can have a flexibility that will allow greater efficiency without any sacrifice of safety.

And that is at least a goal that I would like to think we could think about, in terms of flexibility.

CHAIRMAN CERQUEIRA: Dr. Nag.

DR. NAG: Yes. Dr. Brinker, you are not really opposed to having the whole team. Your concern is two things. Number One, the manpower that you feel in radiation oncology to back you up; and, number two, and it may not be you directly, but some of the other oncology community having a feeling that they may not have a radiation oncologist in a short enough time period to be there; am I right?

DR. BRINKER: I think that is a big issue.

DR. NAG: Now, I think rather than changing the requirements of placing safety in regulation, wouldn't it be better by having more manpower?

DR. BRINKER: Yes, of course.

DR. NAG: And manpower is always generated when there is a need, and when the community feels that there is a need for more manpower, it generates more manpower. So I think that will resolve by itself if this interventional radiology does come in.

The other thing is that almost every hospital that does any kind of brachytherapy procedure requires a radiation oncologist on site who can come in within a few minutes notice.

Because if you have a brachytherapy patient with a brachytherapy source in them, this can dislodge at

any moment, and then you do require someone to be able to physically come in and remote it usually within a few minutes to at least if not hours, but within a few minutes, and so you do have that backup emergency if you do need to do something in an emergency.

DR. BRINKER: Well, your points are extremely well taken, but I would just like to have a chance to address them. One is that in terms of manpower that will be there, and if you build the place, they will come.

I am not so sure, number one, that that is true. And we heard from the point of view of the physicist that if the restrictions prohibited all the physicists from doing all the things right now, there would be an acute manpower shortage that may take a very long time to rectify, and was not really a suitable answer to that particular problem.

The other part of that problem is that it may be that 2 or 3 years from now radiation therapy, at least as it is known today, will be supplanted by some other form of therapy.

And I would hate to think that you are going to build a whole manpower situation of radiation oncologists based on the proposition that you need to

have 24 hour, 7 day a week, coverage for intervascular brachytherapy.

But those things aside, my primary concept is that if at specific sites where you have well trained cardiologists, and you have well trained and experienced medical physicists, and you have radiation oncologists who agree to supply that training and act as supervisory personnel, and who are not necessarily physically present, would that be okay at that site.

Not that it should be general wise, but if that site is where all people agree, could it be a working relationship. And that is the type of flexibility I am requiring with no sacrifice of safety.

CHAIRMAN CERQUEIRA: let me just make one statement, too. As a practicing cardiologist, you have these needs. I have a 43 year old woman who had a vein graph that had gotten a stent, and came in with a stent restenosis, and was flown down from New Jersey.

And the treatment would have been to basically open up the stent and give her some radiation, but she gets in at 10 o'clock at night, and even though we have somebody there who is capable of doing it if we could not get a radiation oncologist to come in to do the procedure, and you have to do a suboptimal treatment.

I think the other point about the manpower -- and I agree with you that the ideal situation would be to have more people. But even if you geared up training programs, you are talking about at least a four year or longer delay for getting people out there who could provide enough radiation oncologists support to do that kind of training.

And I think the technology is certainly emerging and you might find at that point that you have trained people, but there is no need for it at that point. So I think these are issues that need to be addressed. David.

DR. DIAMOND: Just as an individual that does many of these cases, I think in my institution that we are probably number 5 or 6 in the country in volume now.

The way that I see this going is that the -- and particularly in light of the discussion that we had earlier, is that we are going to have an immediate future of a larger volume of cases, and a larger volume of complex cases.

We are going to be moving away from a system where a patient comes in with, let's say, in-stent restenosis of X and U, reflex of the respond, and this is how we are going to treat.

We are going to be seeing a lot more situations where there are going to be novel situations, and a lot more intellectual component to what we are doing.

Probably 2 or 3 years down the line there is going to be a tapering down of volume as things such as coded stents come in or soft x-rays. But in the immediate future, and we are talking, let's say two years, there is going to be an increase in volume and an increase in the complexity of what we are doing.

And, for example, in my institution many of the calls that I field relate to questions from interventional radiologists and interventional cardiologists that are just completely out in left field.

And again as these indications expand, it makes me very nervous about not being a part of it. I am very, very nervous about not being a part of it now.

Now, the other vision that I see is that this is not going to be a technique that is going to be available to every single cath lab in every single hospital across the country.

And just like every single hospital in this country does not do interventional cardiology work, I don't see every single institution in this country doing vascular brachytherapy work as well.

If you talk to some of the companies, the sense that I get from them is that they would like to go and focus this technique in the larger volume centers where they have more quality assurance and quality management oversight, because they realize that the higher volume institutions are getting better results.

So that is the second observation or expectation that I have. The third one that I have is that once again getting back to the time sensitivity. There has to be some minimum oversight that is always present.

For example, let's say a radiation oncologist were available, and a medical physicist were not available in the middle of the night. How do we proceed?

In other words, there are many times when a medical physicist may not be available. So to have it phrased as the way that you put it, Jeff, doesn't make a lot of sense to me. At our institution, we never ever do interventional cardiology work unless we have surgical backup, period.

You know, would we be doing these when there is no surgical background available. So I don't really buy some of these arguments very much. I see this technology being confined primarily to large volume

centers that have busy interventional programs, and that have large numbers of medical physicists and radiation oncologists on staff.

I see the complexity of the cases increasing. The idea of doing this without a physicist or radiation oncologist at a center that does not have surgical backup are things that quite frankly frighten me.

CHAIRMAN CERQUEIRA: Dr. Brinker.

DR. BRINKER: Again, Dave, I think your concerns are quite reasonable, but number one, I still agree with the team approach. I would never do anything without -- and again what I am asking for is a consensus at sites between radiation oncology, physics, and cardiology or radiology, whoever the third party is, to make their own plans as long as they have a plan that guarantees safety.

And, number two, the reality is that any hospital that does interventional cardiology will want to have the ability to treat in-stent restenosis, and here is the reason.

A patient comes in and had a stent 9 months ago, and now comes in with unstable angina. You don't know what he has, and whether he has in-stent restenosis or a new narrowing.

So what do you do? You say, well, we are not one of these radiation centers that we are going to send you off somewhere else. That's not just going to happen.

And, number two, the question about back up surgery, I think that's true. We have backup surgery for non-acute cases, or totally elective cases. We do not have backup surgery for emergency cases, even at Hopkins where we do these cases without a surgeon, or the weekends without a surgeon immediately available.

In fact, there are now procedures done on acute myocardia infarction and intervential procedures at hospitals that have no surgery backup whatsoever at any time.

And there is a push now for doing since stents pretty much obviate the need for emergency surgery, to take out that connotation from the performance of interventional techniques.

Now, all I am suggesting is that the necessity for three man team to do this procedure for most situations is I think an over-commitment of resources, at least at times when some resources are scarce.

And all I would suggest is that there be some mechanism, some opportunity to creatively think

about mechanisms to ease this problem, and to allow if the three specialties would agree, and only if they would agree at least, to have some leeway in the regulatory process.

And to have them push the envelope if you will, in terms of -- or being creative in the way they approach a problem, as long as the safety remains the utmost criteria in those decisions. But it would be a three person decision.

CHAIRMAN CERQUEIRA: Okay. Let's try to get -- some of you have been silent, and so let's start at this end and we will sort of go around. We have heard from the radiation oncologists, the medical physicists, and the cardiologists.

But, Dick, at the Mayo Clinic, where I think you are doing a lot of these procedures, but what do you feel is the -- and keeping the issue of patient and staff safety in mind, and these issues that have been brought up, what do you think would be the appropriate --

DR. VETTER: With the current state of knowledge, I think it is appropriate to continue the team approach. I don't personally have a problem with exploring the relationship between cardiology and radiation oncology, and who does what in the future.

But the technology is rather new, and I think for now the team approach is the appropriate one. That has worked well at the Mayo Clinic. Again, it does become a staffing issue, and it is difficult sometimes for radiation oncology to break free.

But they are getting better at that, and they are anticipating these a little better, and I think they all feel that at this point in time the team approach is best.

CHAIRMAN CERQUEIRA: I think people have mentioned the team approach, and I think one of the slides that you showed -- and I guess it was the ACCC and not the ACR that was proposing the development of training guidelines, or looking at some of these other possibilities. That would be somewhat appropriate.

MR. GRAHAM: I have one question for clarification, because I read the ACC letter, and in particular the affirmation of the team. But I am a bit confused now. I am hearing the endorsement of the team approach, where I think people are saying it in a definition that it is a radiation oncologist or an authorized user, along with an AMP, along with whoever the interventional physician is.

But I am also hearing the potential that a team is being defined as two out of the three. Is that

accurate? And I just want to make sure that I am understanding that when they say that there are affirming a team, are we saying a team that is all three of those as it has been described to this group, or is it any two of the three, or is that what we are debating right now?

MR. WILLIAMSON: A team versus a physical presence. They are not necessarily identical concepts.

CHAIRMAN CERQUEIRA: Well, I think that some of the things that have been bought up are that basically you still have the team of three, but only require two of them to be there if you had a radiation oncologist available to provide issues related to treatment and everything.

MR. GRAHAM: Well, maybe as a lay person to help me as I am trying to shape this going around the room. Most of us are sitting here out of organizations that are gargantuan, and we have huge resources, and we are almost looking at this from the wrong part of the paradine or potentially.

I need to know if at a 350 hospital that does cardiology, and they do interventional cardiology, and let's shape it that they don't even do radiation oncology, and it is two o'clock in the morning, and the patient is coming in, and the opinion is that the person needs to have plasty.

And they have a history that reflects that they may need to have radiation as part of it. I need some guidance on what this group is recommending we are going to do for that very typical community hospital.

Now, if the assessment is that they ought to get shipped to a big referral center, which we all represent, I guess we at least have to acknowledge that there is a certain bias in this discussion, or we have to make sure that we have clarified exactly why they have to go to that type of center.

CHAIRMAN CERQUEIRA: Well, maybe we should address this issue, and I think Dr. Nag and Dr. Brinker want to say something as to that.

DR. NAG: Sure. I think I will address that very issue two ways. Number One, it is theoretically possible what you have just proposed. The problem is that a small hospital of that size, one, will not be allowed to do intervascular brachytherapy because the company that controls intervascular brachytherapy are only going to make it available to a center that has these backups, and small hospitals would not even have this.

MR. GRAHAM: Let me just clarify. The market would demand that they would want to be able to provide it to that hospital, because what I have

described is the predominant market in the United States. We, the big centers, are not the predominant market.

MR. WILLIAMSON: I think to give technically advanced radiation therapy to any site, be it neoplastic or benign, you have to have the appropriate infrastructure in the hospital. Would you give radiation therapy in a hospital that didn't have any physicists or radiation oncologists?

DR. NAG: That was the second part to my discussion.

CHAIRMAN CERQUEIRA: Let's try to keep the discussions focused.

DR. NAG: That was the second part to mine, and the second part was, number one, that the cardiology companies are not interested in giving that technology to a smaller tertiary center, but the second part is that to have this done safely and effectively, it has to be done in a tertiary center that is doing a lot of these per month, and not one a year.

I would never go to a place that is going to do this one a year. It is just like having heart surgery through a tertiary center that is going to do very few of them. And it is very well known that there is a very sharp learning curve, and no one wants to be in a tertiary center that is going to have a learning curve.

CHAIRMAN CERQUEIRA: That may be more an issue of the practice of medicine than radiation safety. Dr. Brinker.

DR. BRINKER: Right. A couple of things. One thing is the size of the hospital doesn't necessarily relate to the size of the interventional population that is being done. Some of the smaller hospitals are basically heart mills if you will.

On the other hand, I would agree that no hospital should under the present circumstances undertake intervascular brachytherapy without the full compliment of backup. And what will happen in these smaller hospitals is the same way these smaller hospitals manage to get cardiac surgery to support their interventionalists.

They will contract and make arrangements to have radiation oncology and medical physicists to do the same sort of support. So the answer to your first question is that if a hospital doesn't have brachytherapy, and a patient comes in with unstable angina, well then the treatment is to do regular angioplasty most likely, and then either ship the patient out for further therapy.

But we have to remember that interventional brachytherapy isn't an emergent treatment for unstable

angina. The first part of the procedure is the angioplasty, and then the adjunct is intervascular brachytherapy to limit the likelihood of a future restenosis.

So I think that what will happen in most of these little tertiary hospitals is that they are not going to say, oh, you have a stent, and you may have a problem. Go to a tertiary care hospital, and they will take them to the cath lab, and they will probably open up the artery if the patient is truly unstable, and then let things go from there.

And you were also right, too, that the small hospitals with the significant angioplasty patient volume will want and will be supplied brachytherapy support, and they will get the full contingent of people.

Again, what I am asking is to think progressively, and allow sites that have three groups that want to work together explore ways to do this in a safe and efficient manner. That's all.

CHAIRMAN CERQUEIRA: Let me just go back to get some comments from people that have not commented. Lou, do you have any -- you are at a big tertiary center like the rest of us.

MR. WAGNER: We do a lot of these procedures, and I have not been involved directly with

any of these procedures. What I hear around the table, and what I can surmise is the following. First of all, I do know that in Europe they are doing things a little differently.

And I have talked to some of the people, and some comments have come to me that in Europe they are the Marlboro Boys, and some of the physicists don't like what is going on over there.

We don't know what the outcome is going to be, but I think that is going to be some experience. I think the team approach with three people or individuals is great, but let's think a little bit out of the box here.

Every place you go, you have different situations. You don't always have the same situation at this institution or that institution, or any other institution. Now, the qualifications of the individuals do vary, and the real issue here is competency in performing the procedures safely. That is the real issue.

Now, what I think Dr. Brinker is asking, and I don't think it is unreasonable, is that you look at the team approach, and you require a team, but you let the team decide whether or not they have the competency

amongst them to be able to perform this in certain different variations of the same thing.

Let the team decide that. They are medically competent, and radiation safety competent, and they have the team approach there, and maybe in some circumstances with the competency that is available maybe only two have to be necessary in the middle of the night.

Maybe in the middle of the night that's a safer situation because you don't have the public all around, and you don't have exposure, potential exposure to the public because of some of the sources that you might choose. That is an issue.

And that is an issue with all of the State agencies. They want to make sure that the public out in the halls aren't going to be exposed too much. I mean, this is the situation.

So maybe the team ought to be given a little more freedom to look at themselves and they have to agree how they are going to manage their patients given their resources, rather than to sit here and decide on micromanagement of every institution by regulation.

The regulation says you have to have a team approach, and then give them a little bit more freedom. I tend to see that as a little bit of thinking out of the box, and some kind of new concepts, rather than to try

and debate this issue as a yes or no answer at this point.

CHAIRMAN CERQUEIRA: Those are very good points, Lou. Jeff, we will come back to you, but Sally, do you have from the perspective of a nuclear pharmacist any input?

DR. SCHWARTZ: Nuclear pharmacy at this point I don't think is a relevant issue. I mean, I work at the same institution as Jeff, and a team approach is certainly what we use. I think whether there is 2 or 3 again depends on how --

CHAIRMAN CERQUEIRA: On the situation and the competence of the individuals.

DR. SCHWARTZ: Yes.

CHAIRMAN CERQUEIRA: Does the FDA have any issues that may be relevant to this?

MR. HEATON: I have some comments on some earlier remarks that I thought I heard.

CHAIRMAN CERQUEIRA: Okay.

MR. HEATON: The remark I thought I heard was that people didn't consider it any different if they were giving radiation to the vascular system or to the neoplastic system, or to something else.

The FDA considered this to be a significant risk for it to go through the 510(k) route. So the FDA

does consider radiation to the vascular system to be different than if you are delivering it to the prostate, for instance.

MR. WILLIAMSON: I said in terms of physical safety and quality assurance.

MR. HEATON: Well, even with safety issues, remember that we are evaluating safety and effectiveness of the device. So safety is a big concern, at least as far as the FDA defines safety in there.

I will tell you that I have a lot of safety issues with delivering radiation to the vascular system that I do not have with delivering it to the prostate.

DR. NAG: Are you talking about basic safety, or are you talking about radiation safety issues?

MR. HEATON: Well, if you are trying to divide the two, I am talking about patient safety.

DR. NAG: And I tried to divide the radiation safety that is managed by the NRC, and the basic safety issue, and the medical safety issue.

MR. HEATON: I was talking about the patient safety issue.

DR. NAG: I agree with you completely.

CHAIRMAN CERQUEIRA: Any other comments?

MR. HEATON: Well, I will say that for at least IDE States for interventional IDEs, they are still

going to require a team approach for any new studies that do come in.

CHAIRMAN CERQUEIRA: And IDE stands for?

MR. HEATON: Investigational Device Exemption, which is what a State has to go through to get a PMA, or premarket approval application.

CHAIRMAN CERQUEIRA: Okay. Good. John. Ruth, any comments?

MS. MCBURNEY: I think that the -- well, I have liked what I have heard on some flexibility and the team approach, as long as each area of expertise is covered.

And when we look back at who does what, not necessarily those particular people have to do that if some of the other people have the expertise in that area.

And it could be that not everybody has to be physically present during the entire procedure in some cases.

CHAIRMAN CERQUEIRA: Now, Ruth, in terms of the agreement States, have you gotten any feedback at the national meetings, in terms of is there variation in the way that States are handling it, or is it too early for --

MS. MCBURNEY: Well, I think it is too early to look at what has been proposed in the new rules. We

have already in our State already included a lot of the requirements for the hodos (phonetic) remote after loaders that are contained in the new rules, in our rules.

And we are already getting requests for exemptions from the medical physicists having to be present during the entire treatment, because in some small hospitals that only use part-time physicists from another city, for example, they don't want to have to be going back several days in a row for sequential treatments.

And if they get it set up and an authorized user is present, and saying, no, the rules are that the physicist has to be there, too, throughout the treatment. So we will just have to live with the rule for a while and see how that is going to work.

CHAIRMAN CERQUEIRA: And you have not gotten any other feedback about how other States are handling it?

MS. MCBURNEY: No.

CHAIRMAN CERQUEIRA: Okay. Naomi.

DR. ALAZRAKI: Just that I would again urge that we not be so prescriptive about this. It is the practice of medicine. I think the team approach is important, particularly since it is still an evolving and

new technology, and I think that radiation oncology is a rapidly growing field.

I mean, I think they can hardly keep up with just the increase in the numbers of cancer patients involved in radiation oncology, and that field is going to grow.

And they are going to be able to meet the staffing needs ultimately, I think, and things may evolve as Dr. Brinker says, and we will be in a different ball game.

But right now we are in the beginning of it, and I think we ought to stick with this team approach, and not be very prescriptive about who has to do what when.

CHAIRMAN CERQUEIRA: Finally, Nekita, as a patient advocate.

MS. HOBSON: Well, I guess my question would be are there any data available that would demonstrate to us the relative risks to the patients in two scenarios, and let's say in the emergency situation that Jeff was talking about, is the patient better off to have the one very highly trained person do a procedure, or wait until Tuesday afternoon three days from now when the full team can be together.

Where does the patient come out on this? I mean, we are talking about real people, and not just sort of theoretical people. If it were you or your mother, how would you want to be treated or her to be treated?

CHAIRMAN CERQUEIRA: Well, as a clinical cardiologist, I think most of the time that you need to do things quickly and certainly with a lot of these patients who come in that are unstable, the sooner that you can initiate the treatment, the better.

There are some delay techniques that you can use, but it is probably not optimal treatment, certainly from my perspective.

MS. HOBSON: So in that case, I would like to have something like where some exceptions could be made based on an emergency situation, rather than be bound by rules that are theoretically intended to protect patients. But maybe in this case are actually damaging patients.

CHAIRMAN CERQUEIRA: Maybe one last set of comments. I have not heard John speak up with emotion, although I did note that he was scribbling things. I don't think we are really at that point, and Fritz, has this discussion been helpful?

MR. STURZ: Well, what I am hearing is that it is too early in the game, and we have got to keep with

the team approach, but maybe there might be some flexibility to say 2 out of 3 have to be present in emergency situations, with a third on call.

That is my overall impression of what I am hearing, and to allow that flexibility in certain emergency cases.

CHAIRMAN CERQUEIRA: Why don't we go to Lou, Jeff, and then John has the last word, and then we will move on to the next subject.

MR. WAGNER: Very briefly, and in brachytherapy, Jeff, you have been comparing the oncology with regard to this kind of treatment in cardiology.

But do you have the emergency situations that develop on a frequent basis in oncology, or are most of your brachytherapy assistance planned, where everybody knows what time it is going to be, and it is going to be here.

And are you experienced in the idea of meeting with an emergency when you have the patients arrive at your hospital and they need treatment right way, and then you have to have people on call come in immediately to do that.

I mean, I seem to think in my naive imagination as a diagnostic physicists that there is probably a huge difference here with regard to exigency

of the procedure, which is really what the issue comes down to, and then that comes down to care of the patient.

CHAIRMAN CERQUEIRA: Let Dr. Nag make one comment, and then Jeff.

DR. NAG: Well, I am on call all the time because of the same thing. I have been dong emergency intervascular brachytherapy radiation all the time.

The surgeon would go in and they would try to take out the tumor, and we wouldn't even know about it, and all the while the patient is wide open, and can you come up and radiate the tumor bed, and we would be up there in 15 minutes to 20 minutes.

So it is our response time and it is much faster than any response time that I have needed to give to my cardiologists, because cardiologists usually are much better, and they give me more than a few hours notice.

I have the time to even talk to the patient beforehand, and many of the emergency patients I have talked to, and I have put the catheter in first, and talked to the family, and so our response time --

CHAIRMAN CERQUEIRA: Those are good points, although I guess some of the situations that Dr. Brinker was referring to was that most oncology surgeries are

elective, and a lot of the cardiac problems with unstable patients are in a more random manner.

DR. NAG: You probably need a better set of radiation oncologists in your hospital.

DR. BRINKER: We have a very good set of radiation oncologists, but believe me in all honesty, when you are doing a hundred procedures a week, and you are doing them 24 hours a day and on weekends, it is a major commitment, especially since some radiation oncologists -- and you may be one of them -- feel that they have to see every patient before the procedure.

That is impossible, because they would be seeing 10 patients for every two that actually need this procedure, even if they could see every patient. So clearly unless you feel there is some inefficiency and that the whole house of cards is going to fall down.

CHAIRMAN CERQUEIRA: Okay. One last comment from Jeff, and then we will go on to the next item.

MR. WILLIAMSON: I think this whole discussion has been rather diffusely and not very targeted on what the issue is. I think with the exception of one comment, and maybe John meant it rhetorically, I don't think that anybody has set that there should not be a team approach.

That there does not need to be in the structuring and organization of this procedure all three types of individuals being involved, and I think the discussion should be focusing on who needs to be where when, and does team approach necessarily mean all three people have to be in the operating room from the start to the end of the treatment.

And again I think I will go back to the way the existing regulations are written, 400 and 600, and they are sort of graded based on response time, technical complexity, and I forgot to mention -- and this is important, too -- the public health consequences of an uncontrolled source.

So Beta and Manual Iridium pose much smaller risks than if you have a 12 query or high dose rate source running loose. I really think they are different, and I think that the sort of graded level of physical presence needs to be carefully calibrated to that, and so I really agree with the idea of flexibility --

CHAIRMAN CERQUEIRA: I think basically that the team approach with flexibility, with some encouragement to make 2 of the 3 present in some situations where you can't do things electively, and there is a certain urgency. Those are good points, but I think we really need to go on to the next subject.

MR. WILLIAMSON: Well, to just sort of finish my last comment, I think there is a lot of guidance in the existing regulations where those boundaries fall, and who needs to be where when.

CHAIRMAN CERQUEIRA: Good. Excellent.

MS. HOBSON: But not to withhold urgently needed treatment based on some rule. I mean, not that the rules are bad, but if they are a stumbling block to good patient care, then they are not doing their own job.

CHAIRMAN CERQUEIRA: Okay. We will give Nekita the last word, and we will go on to the next topic. Fritz, thank you very much, and the next item is Authorization for Broad Licensees to Utilize New Brachytherapy Procedures. John Hickey. So we have not really left it yet have we.

MR. HICKEY: Good afternoon again. I don't have a visual presentation. I do have a one page summary. Much of this was discussed in the last meeting, but I kind of wanted to try to clarify and bring this to closure.

We want to talk about broad licensees, and they by definition are not restricted in the way that limited specific licensees are and how they use radioactive material for medical purposes.

They have a radiation safety committee and other management, and procedures in place to evaluate authorizations for various uses, and so that gives them broad flexibility.

When we came up to these newer procedures, we found that even for broad licensees that we needed to take a look at how these were authorized, because again the traditional brachytherapy envisioned using sealed sources to treat cancer.

And now we are finding that liquids and gases might be used for that purpose, and also that there would be treatments for intervascular brachytherapy and not just for cancer.

So to some extent, Part 35 didn't quite fit the situation, and with respect to the broad licensees, in most cases it didn't matter. But we found that it did matter in some cases how Part 35 was worded, particularly with the requirement to prepare a written directive.

And I noted Dr. Wagner's comment earlier, I believe, that just the fact that you get into having to prepare a written directive causes a prescriptive aspect to the regulation. So here is an example of where this could get you into a more prescriptive mode.

So we took a closer look at this, and to some extent we asked and answered several questions, and

taking into account the advice of the committee from the last meeting.

And that is that for these new types of technologies, where there may be some little wrinkles that need to be considered, how much flexibility should the broad licensees have.

And our conclusion was that we should -- that if it is in a gray area, make the decision on the side of giving the broad licensees -- and in general licensees, but in this case broad licensees more flexibility rather than less flexibility, and that is consistent with having a more risk informed performance based approach.

So if there is a little bit of a twist on how they had to prepare the written directive, we are going to leave that up to the broad licensee. We are not going to have them come in and get NRC approval on how to prepare a written directive every time they get a new technology.

And the New Part 35 is worded accordingly. And we have also -- and a couple of examples would be for -- well, there are a couple of areas in the current Part 35 where you don't have to specify the treatment site in advance in preparing the written directive.

And that has been clarified in the New Part 35. Also, it assumes that you are treating with a certain number of sources or source strengths, and again that assumes a sealed source.

But if you are dealing with a liquid or gas, that doesn't quite fit. So you could express the treatment in terms of the total source activity, rather than worry about how many sources.

So that is the general approach we are going to take, and we think that is consistent with the advice of the committee.

CHAIRMAN CERQUEIRA: I will open it up for discussion. Dr. Nag.

DR. NAG: I agree with you, but the way that the New Part 35 definition is on your paper, before a implantation in the treatment site, the radionuclide and the dose, I think that it shouldn't be and the dose, because we may or may not know the dose beforehand.

It could be "and/or dose activity." Because if we do a permanent implant, we won't know the dose. That should be corrected.

MR. HICKEY: Let me double-check that for you, but we can continue the discussion. I have the text right here. Go ahead.

CHAIRMAN CERQUEIRA: Sure. Other items of discussion for John?

MR. WAGNER: I think it is great. End of discussion. I think it is great.

CHAIRMAN CERQUEIRA: It's great. Anybody opposed to that? Jeff, you are happy with it?

MR. WILLIAMSON: Well, let me just ask. This New Part 35 definition is the one that is in the Part 35 that is before OMB now?

MR. HICKEY: Correct.

MR. WILLIAMSON: Word for word?

MR. HICKEY: That is what I am talking about, but I am checking the wording now.

DR. NAG: And in that case, even after that the --

MR. WILLIAMSON: I think you have to go to the definition section and see what dose says. I can't remember if it is in the New or Old Part 35, but I think it says or that it may define dose as the product of source intensity and treatment time.

And that is sort of important I agree, because some treatments are not prescribed in terms of physically absorbed dose, but they are prescribed in terms of total reference, the product of source, strength and time.

DR. NAG: And even here after implantation, you still have the number of sources which may or may not be applicable.

MR. HICKEY: Forgive me, but just to clarify. You are correct, Dr. Williamson. The dose can be the total source strength and exposure time, or the total dose.

DR. NAG: Okay. And then after implantation? Again, here you would take treatment site, number of sources, and again that may or may not apply.

MR. HICKEY: Correct. That's where we give a little bit of leeway in specifying source activity rather than number of sources, depending on the application.

CHAIRMAN CERQUEIRA: Okay. So anybody else wish to make comments? Well, that's good. We are ahead of schedule. Maybe we should try to just keep going now to additional items.

MR. HICKEY: Well, I have a question on the previous topic, and I apologize, because we went overtime. But I noticed that there was still some discussion going on, and my question is -- if the chairman will indulge me.

CHAIRMAN CERQUEIRA: Sure.

MR. HICKEY: And it has to do with the team approach, which assumes that the interventional cardiologist is not an authorized user. We think in the future that we are going to reach the point where the cardiologists are also authorized users.

So my question is what does the committee envision as -- how do we define or describe the role, or what is our concept of who the interventional cardiologist is, and I am looking at this from the point of view of a regulator.

I am describing the members of the team, and so if the interventional cardiologist is not the authorized user, what is the role or how do we define who that is?

CHAIRMAN CERQUEIRA: Anybody care to answer that?

MR. WILLIAMSON: Do you mean functionally what is the authorized users purpose; is that what you mean?

MR. HICKEY: No, this is -- if there are people there -- the medical physicist and the authorized user are defined by the regulation. The interventional cardiologist is not there. So if we are going to put out guidelines that assign a role to the interventional

cardiologist, how are we going to define who that is or describe who that is?

DR. VETTER: I don't think the NRC should do that. That is a medical problem and the team will certainly -- I mean, they have to involve the cardiologist, but that should ge left up to the medical center on how they want to define that team, and who that interventional cardiologist is.

DR. DIAMOND: We are going to give Lou a stroke.

MR. HICKEY: Then do we need to mention the interventional cardiologist at all in our guidance?

CHAIRMAN CERQUEIRA: I think Dr. Diamond's point was that it may be a cardiologist, but it could be an interventional radiologist in some cases. So you need sort of a -- you know, a physician who has been approved to do the procedure, which is really sort of a hospital --

DR. ALAZRAKI: Purview.

CHAIRMAN CERQUEIRA: Right. I mean, they decide who has privileges to be in a cath lab to do interventional radiology procedures. You know, the issue may come up, and which really relates to this committee, is that if you are going to allow radiologists to be the

authorized users, then what sort of training should they have.

But we have kind of decided that at this point it is still a team approach, but these other issues of the requirements for the non-authorized user involved in the case, I think that is defined by hospital requirements, and by professional medical societies, and shouldn't really be defined by the NRC. Ruth.

MS. MCBURNEY: Well, going back to what expertise is needed, and you have that list, and you have patient preparation, and introduction of the source train, and the removal being the responsibility of the interventional cardiologist, without naming that person by name, someone that has the expertise to do that as part of the whole procedure would be appropriate.

DR. NAG: I would like to respond to that. Since very soon this will be both in the cardiac, as well as in the vessels, instead of naming interventional cardiologists, you can call them interventional physician, or intervascular physician. That will be open to anybody, number one.

And, number two, on Mr. Sturz's list, I am aware that at most hospitals the introduction of the source and the removal of the source train is not done by the interventional cardiologist. It is done by radiation

oncologist. So that's why from what has been shown, I ask you how or where did you get this.

CHAIRMAN CERQUEIRA: Jeffrey.

MR. WILLIAMSON: I have a question for the two cardiologists. To what extent do you use Fellows and Trainees who are not board certified in interventional cardiology to do procedures, and do you insist on physical presence when you are there all the time?

Do you allow them to do procedures when you are not physically present? For example, somewhere else in the hospital. This is an informational question, and I really don't know, because as you can see, when you become an authorized user it becomes a major struggle of who can substitute.

CHAIRMAN CERQUEIRA: At our institution the requirements are that you have to be approved by the -- we have a cardiac catheterization committee that approves who can do procedures by themselves, and Fellows don't qualify.

So we have an attending present at all times in the cath lab. I don't know what it is like at Hopkins.

DR. BRINKER: There is always an attending physician scrubbed with a Fellow, or a Physician's Assistant sometimes assist in these procedures. Fellows

do not do interventional procedures by themselves, nor now do they even do diagnostic catheterizations by themselves without a scrub attending at the table.

There are two reasons for this. The first reason is patient safety, and the efficiency of the whole system, as well as teaching of the fellow; and the second system, which is possibly a little bit related, is the fact that Medicare insists that the attending physician was scrubbed and at the procedure. So that sort of makes life easier.

MR. WILLIAMSON: So then you could use board certification as a defining --

DR. BRINKER: Well, board certification is very antsy in cardiology for a couple of reasons. First of all, there is a new interventional board which not every interventionalist has taken yet.

And that there are qualified physicians who have finished Fellowship, and who even have not been board certified in cardiology yet, but who have the ability to perform independent catheterizations.

So boarding is not -- and unlike the things that we heard earlier for other specialties, boarding is not a qualification or a necessity for physicians to do either catheterization or interventional procedures.

CHAIRMAN CERQUEIRA: Does that answer your question?

MR. WILLIAMSON: Yes.

CHAIRMAN CERQUEIRA: All right. At 2:30, we are supposed to discuss additional items.

MR. HICKEY: Yes. Dr. Wagner wanted to introduce this topic if he could.

CHAIRMAN CERQUEIRA: Sure.

MR. HICKEY: I would like to remind everybody that I believe that this is your last meeting, Dr. Wagner.

MR. WAGNER: Yes, my last meeting, and so I want to leave you with a little more work. There is a handout coming around with regard to two issues, which I think the ACMUI ought to start considering with regard to advice to the NRC on some issues.

And they have all come up because of the changing times, and I want to bring them to your attention. I thank the NRC and the Chair for giving me this time to present this.

I am not presenting this as something that I think we ought to discuss here and now, but I am presenting this as something as issues that I think are going to be future issues to address, and trying to get the ball rolling on some of these things.

For example, Issue Number One, Part 20 exposure limits apply to all types of radiations, and not just to those generated by-product materials.

This is a problem in medicine. Many physicians perform nuclear medicine procedures and fluoroscopy interventions. So we are mixing now x-rays with by-product material radiation.

An effective dose equivalent is usually the limit that is applied, but it is impossible to measure. Anybody that thinks that they can measure accurately the effective dose equivalents is misguided. This is not something that is possible to do.

So how does the NRC and agreement States apply limits to individuals who mix exposures? This is a major problem. So now we need reform in methods of occupational risk assessment, and enforcement, because basing violation type enforcement on a mixed EDE that is impossible to measure is totally impractical.

It is not a practical solution. The fallout, and we are all familiar with this, violation of enforced regulation discourages faithful risk monitoring. How many physicians sit there and have told me that you are not going to prevent me from practicing.

I won't wear my film badge, and it is impossible to go around and make sure that everyone is

wearing a film badge all the time. It is just silly. We are discouraging these things, and we shouldn't be doing this.

We want them to wear their film badges, and we want to know what the radiation environment is, and we don't want regulations that discourage the practice of medicine.

So we need to develop techniques that reward good practices of risk monitoring. We need to change things. Now, this has been stimulated by certain messages that have come across my E-mail recently, where these issues are becoming problems, and it is quite clear that problems are being raised.

And certain bodies might calculate effective dose equivalent one way, and other bodies might calculate it another way, and they all come up with different numbers.

I mean, it has gotten to a point of silliness in some regards. I know that the State of Texas used to have a rule -- and I don't know if it is still there because they have changed the rules so many times recently, but there was a rule where if you exposed a physician to more radiation, you could legally lower his dose.

I mean, there was a rule, and they had that in there, and you could lower our dose significantly by exposing yourself to more radiation, because you crossed the boundary and now you could apply a different rule of calculation. Total silliness, okay, for things that aren't uniform.

So my recommendation is that the NRC should review its rules on occupational dose limitation to determine, one whether the NRC has legal authority to incorporate risk from non-by-product material into their regulations. That's number one.

And, number two, to investigate risk informed methods of regulation based not on dose limits and numbers that are generated and meaningless, but on practice of risk assessment and an informed work force.

It is a new concept and it is a new idea that I wanted to put forth to this committee. The idea that numbers aren't what is really important to generate.

What is really important to look at is whether nor not the facility has a significant risk assessment method in practice, and they are using it properly to inform the work force about what they are being exposed to. That's really what is important.

So that is the first issue that I wanted to raise and bring to the committee's attention. I think it

needs to be addressed. My second issue is that conditions for licensing are specified by licensing agency and are listed on the license. This is a fact and we are all familiar with this.

Regulations state that an agency may require conditions to ensure safety. That is perfectly sensible; and conditions or regulations that are not subject to public review. That's a fact, that are put on your license by the agency.

But now I ask who in the agency decides on conditions, and what guidance is followed to ensure uniformity, and are the conditions risk based. I think these issues ought to be addressed, because it is a way that the risk based rules can be circumvented.

I would like to recommend that the NRC review its policies in creating licensing conditions and make modifications as necessary.

And define criteria under which conditions are necessary; i.e., things like the uses uncovered by the rules, or the facilities to have repeat violations. These would be the criteria by which a condition would be imposed.

Number Two, to ensure that the conditions are risk based and not just arbitrary. And, three, to

ensure uniformity and fairness in requiring licensing conditions.

Now, this was brought up by several issues that I had experience with. One is that we have a meeting in Houston, Texas, amongst radiation safety officers at our facility. We are a huge medical center, and we have an enormous number of radiation safety officers all congregated with a couple of square miles.

And we get together and we talk about these things, and we found out that different facilities are treated differently, and that all of the conditions are different, and it all depends on who you had as an oversight or overseeing your license when it was made up.

I just had a recent situation where a condition was put on our license, and it was arbitrarily put in there. We asked why and he said because I don't believe that you are going to do what you say you are going to do. I want you to do this extra thing.

And then we asked, well, this is in the rules that we stated in our policy and procedures, and why do you want us to do this extra documentation. You know, it is not necessary and we don't want to do this. This is silly.

And the idea was, well, maybe if you discussed it with us for a couple of months, and we might

get around to agreeing with you. But if you want it approved right away, you had better agree to it. This was a problem. I didn't see this as fair.

And then it was brought up again in the letter by the Society of Nuclear Medicine and the American College of Nuclear Physicians, that these conditions could be imposed on licenses, and they seem to have a problem with it.

So it seems to be much broader than just the personal experience. So I think these are two issues that I think are important to address at this point.

And I think that the ACMUI would be doing a good service to the nuclear regulatory commission to try to give some advice with regard to these issues, because the future of medicine is changing, and it is changing rapidly, and we need to meet these problems at this time.

CHAIRMAN CERQUEIRA: Thank you, Lou. Those are very good points. Any comments? Jeff.

MR. WILLIAMSON: Well, I think Issue Number 1 is really very, very important. And in fact it has been brought into focus at Washington University for the very reason that we were talking about just earlier, which is intervascular brachytherapy.

The fact that when cardiologists become involved in the delivery of treatment using by-product

materials, all of a sudden all of their exposures from floral exposures become subject to Federal oversight, and this is has actually provided one reason why the radiation oncologist should be physically present. I mean, this is one solution.

The radiation oncologist can do the procedure and the cardiologist can step away and then preserve their ability to avoid Federal oversight.

DR. BRINKER: What we really need is the radiation oncologist to stand between us and the floral.

(Laughter.)

MR. WILLIAMSON: Precisely, and as you can see, there are more creative and clever variations on this theme, but it is a serious problem, and I think the fact that it points out that the -- and I think Lou has a real point here.

That there really is an awful lot of expense, and in some cases maybe loss of quality of medical treatment needed to satisfy a very arbitrary rule which in many expert's minds has questionable data behind it.

You know, are there such severe risks associated with personnel exposures, at least to the point where there should be such adherence to her rule that 4.99 is okay, and 5.01 is unacceptable.

CHAIRMAN CERQUEIRA: Those are good points. Dr. Nag.

DR. NAG: Would you clarify your point three on your issue number one, or 13, that it would be impossible to measure the annual .5 that the mixing exposure -- I mean, I just want to know a little bit more about that.

MR. WAGNER: The effective dose equivalent is based upon individual organ doses of the body and it is based upon a waiting factor assigned to each individual organ dose, and the waiting factor itself is based upon the proposed radiosensitivity of that organ, which is based on some very questionable data.

So if you are wearing a lead apron in a fluoroscopy room, and calculating your effective dose, it is quite different than if you are exposed to a nuclear medicine source.

Furthermore, most of the calculations don't even take into account body attenuation to internal organs. I mean it is also some arbitrary how we do this thing, and it is a prescription of how to calculate a number, rather than to really define a safety issue.

And I think that we are getting away from that philosophy of having these prescriptive ridiculous

things that don't really achieve what you are looking at, and let's look at what we are trying to look at.

Let's look at your program of risk monitoring, and whether or not your risk force is appropriately informed of the risks they are taking in the environment that they are working in.

CHAIRMAN CERQUEIRA: Jeff.

MR. WILLIAMSON: Maybe a question to John Hickey, and if he could clarify what NRC's understanding of what Part 20 implies regarding this issue of non-by product exposures.

MR. HICKEY: yes, and this is partly a legal issue, and I am a technical person and not an attorney, but the way that Part 20 is worded is that the total occupational radiation exposure that a person gets should meet the NRC limits.

And that assumes that some of the exposure is from NRC licensed material. That's how we get into the picture. So if somebody gets, for example, 3 rem of exposure from accelerators, and 3 rem from NRC regulated material in a year, then we would be concerned about that. The intent is the workers' total exposure should be controlled.

CHAIRMAN CERQUEIRA: All right.

MS. MCBURNEY: From a State's perspective, of course the States regulate all sources of radiation, and so we do have to take into account the total occupational dose.

We have -- and many of the other States -- have incorporated the NCRP recommendations figuring some sort of EDE when there is an apron present, and they are wearing a badge both outside and inside the apron and could calculate that.

And so I think we are trying to make attempts to do that, but in a regulatory arena you do have to have some sort of limit in the rule, and not just sort of nebulous, and risk-informed, and you know the risk, and whatever you get that's okay.

MR. WAGNER: With all due respect, Ruth, I understand that from the point of view of regulation, but I think we are in a box, and I think we can think outside of that box.

Numbers don't have to be a matter of less than no violation, or more than a violation. The numbers can be used as limits or guidelines at which certain action items are taken, and certain risk informed issues are addressed.

But not necessarily that with this number that you have not violated and this number you have

violated the rule. And we can get away from that thinking, and we can get more into the thinking of using these numbers more as a guidance for advice and practice, and whether or not the program that they have instituted is a good risk-based program of monitoring, and not a matter of number generating.

And really with the numbers and the way that they are calculated, and all the numbers that are used, whether it is NCRP or not, they are all wrong because they are all based upon some badge monitor or somewhere on an apron, and then what happens when they use a face shield that blocks the badge.

I mean, it totally makes it a ridiculous number. So I think we have got to get away from that, and I would like to see thinking outside the box now for risk based rules, and I think we can get away from those numbers.

We don't have to have them, and I think there is creative ways to do that and still keep a very sane and safe working environment.

CHAIRMAN CERQUEIRA: David.

DR. DIAMOND: Lou, one thing that you mentioned was very disturbing to me, and that was your second issue, which seemed to me that the colleague that you were referring to was the subject of some fickle

treatment by our regulator that had no real basis, no logical basis, and it was almost at a punitive nature, or a vindictive nature almost in a quality.

And of course that had no potential for public review and therefore disputation. That to me is the most disturbing thing that you have mentioned so far. Is this something that happens on a regular basis? Is this an antidotal event?

MR. WAGNER: I don't meant that to be a matter of being punitive, or vindictive, or anything like that. I don't think that is the motivation. I think it is a matter of regulators having a mindset about what is important and what is not important, and then they apply certain rules.

I didn't know where this new addition was coming from and I really was not the direct contact on the issue. I was the guy in the background working out the issue, okay?

And it was a duplicative issue. It was a matter of forcing additional documentation on a prescriptive basis every week to ensure that certain white tests are done, which was already in the policies and procedures that you do the white tests every week in the first place.

Why did we need this additional documentation so that the RSO checked to make sure that they were being done every week and then sign the documentation that said that. It didn't seem right to me, but I don't know that it is vindictive or anything like that.

To me, it is arbitrary, and that to me is the issue. I think uniformity in the application of these conditions for good reason is what is necessary, and I want to emphasize that is a State agency, and an agreement State and not at the NRC.

But all of this guidance comes down from the top and from the NRC.

CHAIRMAN CERQUEIRA: Jeffrey.

MR. WILLIAMSON: At Washington University, we have had similar incidents, too, with the NRC, and this is NRC because we are not an agreement State. For example, if your institution is so unfortunate to commit a violation, what our experience has been is the inspectors who come and deal with this situation can actually sort of prescribe punishments that go well beyond the pale of the rules.

So, for example, in one case they ruled basically that we had to document that we checked the

condition of the implants by an authorized user once each shift.

Now, of course we checked the implants quite frequently, but there is no requirement in Part 35 that says that we have to document such a check.

So they simply made up basically a prescriptive rule, especially made for us, because they thought that we needed this extra Federal oversight. Now, I am certainly not arguing against carefully checking patient's implants on a periodic basis.

I think that really the NRC has no authority to be involved in this. Their oversight should be limited to whether we are following the rules, and if we have a violation, we of course honestly report it, and this was a self-detected event.

So I think it does happen all the time. I could mention also licensing experiences, where we have had the same thing, especially with a newer or untried technology.

There is a tendency to sort of make up rules sort of on the fly, or base them on Cobalt 60 teletherapy, or some existing standard, and then inappropriately adapt that standard to the new technology.

CHAIRMAN CERQUEIRA: Good. Well, I think these are very good points, Lou, that you brought up, and I am sure that John Hickey, who is going to be coming up to microphone for the next presentation will take all of this into consideration, and take appropriate actions, right, whatever they may be. Well, good.

Let's go on to the next topic, and maybe we can cover that before the break, John, and that is the rejection of medical waste by local landfills. This is an issue that we have discussed before.

MR. HICKEY: Yes, Mr. Chairman, I think we should be able to cover this briefly, but I am available to entertain questions. I think most of you are aware of the general problem.

Medical licensees and other licensees can dispose of certain materials that are slightly contaminated as normal trash, which means that they can go to a local landfill that accepts general refuse, or there is also disposal sites that accept hazardous waste, but not radioactive waste, but it may be hazardous for other reasons because of its med-bio hazard contents or whatever.

And many waste processors and landfills have installed radiation alarms as a preventive measure,

because there is all kinds of ways that radioactive material can get into a disposal facility.

So we frequently get reports several times a week among us and the States of these alarms going off. And the problem is that the types of waste that can trigger an alarm can be authorized or unauthorized, and there is no formula for a radiation alarm system that can make the distinctions that would need to be made.

In some cases, the authorized versus unauthorized material cannot be distinguished by a physical device. In other cases, the sensitivity is not a determining factor because you could have material that is shielded, and therefore you would want your alarm to be more sensitive to find material that is partially shielded.

And in some cases the material is very low contamination, but low levels of radioactivity, but might still be unauthorized. So they want the alarm to be in place for that purpose.

So we get reports sometimes that the waste generator is a hospital, and in some cases it was an unauthorized disposal, and upon review the hospital says that that should have gone out as radioactive waste and we let it go out as non-radioactive.

But in other cases it was legitimately disposed of. So the States -- the NRC doesn't regulate these refuse facilities and in many cases they are State regulated, but not by the radiological health people. They are regulated for some other purposes.

So I don't -- we don't see an easy solution to this. What we have done is encouraged communication that the hospitals and others need to be aware of what monitoring systems are in place at the disposal facilities.

And use the same or equivalent monitoring when the stuff goes out the door so that they know what is going to pass. And if they know that something is not going to pass, they need to negotiate that in advance and not just wait until the alarm goes off.

DR. DIAMOND: John, I understand that some of these systems are very, very sensitive; is that correct?

MR. HICKEY: Correct.

CHAIRMAN CERQUEIRA: I have been at agreement State meetings, and that's a big complaint, and it is a big expense for the States, because sometimes for non-hazardous levels of radiation, they have to go through and find it, and it is very time and money prohibitive. Jeffrey.

MR. WILLIAMSON: What forces the landfills to set the threshold so low that you are getting these reports all the time?

MS. MCBURNEY: They do themselves.

MR. HICKEY: As I said, the material could be partially shielded. So they are not assuming that they are looking for unshielded materials. So that they set it at a state-of-the- art sensitivity. Go ahead.

MS. MCBURNEY: Some of the manufacturers of these detectors will set the sensitivity themselves, because the landfill owners don't know. They just say we want to pick up anything that we can.

The conference radiation control program directors has developed some guidance for landfill operators, and in setting the sensitivity of these, and made some recommendations. But the landfill operators don't have to comply with that because they are not regulated by them.

MR. WILLIAMSON: But it would seem that you wouldn't have to investigate it if it were under a certain level.

MS. MCBURNEY: Well, the landfill operator would just call and say I have got a hit, meaning that the alarm has gone off. So the State investigator --

MR. WILLIAMSON: Has to run out there and at a minimum, you have to do a check of the exposure rate at one meter and decide whether to do anything else. But you are not forced to do anything more than that.

MS. MCBURNEY: Right.

CHAIRMAN CERQUEIRA: Although some of the States complained that they have to clean it up, and first of all find --

MS. MCBURNEY: You know, first find it, and then find out if it is just a piece of bed linen or a diaper from a hospital, or if it is a sealed source.

MR. WAGNER: So what are you asking us for?

MR. HICKEY: This was an informational item primarily, and you are welcome to comment. One of the members suggested that we discuss this during the meeting, and so you are welcome to comment.

MR. WILLIAMSON: Well, I think this is a good example of the regulators, or like the regulators that we have in the regulated community, and our professional associations make guidance that we make available, and we try to promote its use, and it is a really good thing to do.

And maybe that would be the only long term strategy, but a question that I have is what is the level

of compatibility of 35.75, which I assume must be contributing to a lot of this.

And a follow-up question to that is how much of this is due to the change in the patient release rule?

MS. MCBURNEY: If it is coming from the hospital, it is not due to release of patients. It is due to their normal nuclear medicine waste. Now, we in Texas have a unique rule that allows certain concentrations of short lived material that is less than 300 days, half-life, to go to the type one sanitary landfills. And so we have got other waste going there, as well as just the hospital waste.

CHAIRMAN CERQUEIRA: Naomi and then Lou.

DR. ALAZRAKI: As I understand it, Ruth, the waste sites monitor on waste as it comes in. So they can usually identify the origin of the waste which set the alarm off.

And if they can identify the origin of the waste that set the alarm off, they can call the responsible parties and say come get it. And in general the responsible parties -- it happens very little to my knowledge in my area.

MR. GRAHAM: Let me clarify that in Michigan they say send the truck back. In Michigan, they just

send the truck back, and once you pay for a truck going into a dump, and coming back, you don't do it twice.

DR. ALAZRAKI: Right.

MR. GRAHAM: So you get a really upset teamster driver, and you don't do it twice.

CHAIRMAN CERQUEIRA: That could be risky. Lou.

MR. WAGNER: I think the problem is a very interesting one. First of all, has anybody has any experience with them returning waste to a home? I don't think that has ever occurred, although I do know that toothbrushes and things like that --

MS. MCBURNEY: Diapers.

MR. WAGNER: Yes. Usually what happens is that from a hospital it is usually a radioactive material that has been disposed of into a baby or into a patient, and so it is legally disposed material, and then it gets into a diaper or something, and then it gets shipped out.

Other times it is catheters from the cardiac lab that get thrown into the normal trash for some reason because somebody was negligent about doing that, and then that gets caught. And that is actually the difference.

But I don't think that we should separate whether or not it is -- that under those circumstances, I really don't think as far as safety is concerned that

we should really separate whether it is properly disposed of or not properly disposed of.

The issue is whether it is a safety problem. I have always contended that the waste itself is more of a safety problem than the radioactive material that is in there most of the time.

The biggest concern they have is whether or not there might be a source that really is something of a concern, such as a cobalt source, or a cesium source, or something like this.

So it seems to me that this would be a -- I don't know, maybe a possibility for some really good grants and research to develop detectors that can separate this stuff out for these facilities. We have got the technology to do this stuff. We ought to be able to separate it out.

I don't know. Could it be a recommendation of the NRC? Can the NRC issue a request for proposal on the development of such detectors and things of that nature?

DR. VETTER: It may already exist.

MR. WAGNER: It may already exist then, and they should be able to automatically be able to channel out whether or not it is an acceptable or not acceptable

radioactive material, and they have to recommend to the waste facilities that they start using these things.

CHAIRMAN CERQUEIRA: Richard, and then John, and then we will wrap up.

DR. VETTER: There are multi-channel analyzers that would easily tell the operator what the radionuclide is.

MR. WAGNER: But does it automatically check it?

DR. VETTER: Well, yes. The same detector, and just hook it up to the multi-channel analyzer. But it is expensive.

CHAIRMAN CERQUEIRA: And you don't have the expertise at these sites to do that.

MR. WAGNER: You need equipment that would automatically do that and pick that up.

MR. GRAHAM: I guess I would conclude that if you can find a foundation that wants to pony up the money to do that research, fine, but if you are proposing Federal tax money being allocated to do that, I would not recommend it.

CHAIRMAN CERQUEIRA: All right. Well, I am not sure where else you would like us to go with this, John. I think you have heard some general comments.

MR. HICKEY: We just wanted to hear the general discussion.

DR. VETTER: I don't know if the NRC has considered any guidance to hospitals, but there are things that hospitals can do. Number One is to make sure that they follow their procedures, which I think most do, but in terms of 35.75, they can instruct incontinent patients, for instance, to hold their diapers in the garage for a week or two. We do that.

I mean, most patients aren't incontinent, but occasionally that does occur, and so you simply have to instruct them a little differently than you do the normal patient. And I don't know if that would be useful guidance, that kind of thing. And if in fact most of this is coming from medical sources.

MR. WAGNER: The best solution is John's solution, because we have experienced the same thing, and once you get that expense thrown back at you, what you do is you invest money into a detector that is just before the garbage goes out to the waste facility.

And anything that goes by it sets off that alarm, and it gets brought right back into a storage room, and just sent for decay, and that is the best solution, and maybe that kind of a recommendation could

go out to users and say there is this difficulty, and to avoid this expense, you may want to consider this.

CHAIRMAN CERQUEIRA: I definitely put the expense that the agreement States have to bear fairly often on the offender. All right. Fred Brown wanted to make a comment to a couple of the issues that came up before.

MR. BROWN: Thank you, doctor. Yes, there is some good points that were raised relative to license conditions and guidance, and the NRC is using standardized guidance for license conditions.

And what may appear arbitrary to one may not appear arbitrary to the other any time two of us sit down and discuss the issues.

We are currently -- and literally yesterday, we were talking about is there a prescriptive guidance that we can get out of our instructions that will reduce the burden on you and us, and that will make us more efficient.

And specific ideas are always welcome. They can be provided directly to John or myself, or to the regions. And there is a lot of common ground I think going forward in that area.

One thing that I do want to be real clear on though is that there are things that are inappropriate

for NRC employees to do, and they are taken very seriously, and if an inspector forces a requirement on a licensee that is inappropriate, it is contrary to the regulations, and it is contrary to our guidance, you should contact as a licensee the region or headquarters, or the Inspector General for the Nuclear Regulatory Commission.

And we take it very seriously, and I would hope that everyone would leave the room with that understanding. There is no question that if a specific case is provided to us that we will follow up on it.

MR. WILLIAMSON: If I could just ask a question of clarification. So you are telling me that there is -- and if I am hearing what you are saying, and understanding what you are saying, there is no legal basis that as the result of an enforcement action following a violation to impose additional requirements on the licensee that are not in the license or in the regulations?

MR. BROWN: The only legal authority for the NRC to do that is through issuing an order. A notice of violation typically requires a licensee to provide corrective actions. Those corrective actions are at the discretion of the licensee.

If we have concerns about the adequacy, the formal process is to deal with licensees and to reach a mutual understanding. But to have an inspector tell a facility that you have to fix this as follows is not appropriate, and it is not consistent with our policy and procedures, and it will be dealt with on a case by case basis.

MR. WILLIAMSON: So can we be ordered as licensees to follow procedures which are not part of the rules, or existing documented licensing guidance?

MR. BROWN: The Commission has legal authority to issue an order to maintain public health and safety, but that is not something done by an individual inspector.

CHAIRMAN CERQUEIRA: Richard.

DR. VETTER: Just to reflect on that. Our experience with NRC has been extremely favorable over the years, and in one case we did have an inspector who cited us, and I tried to point out to him that he was wrong.

He was adamant that he was right, and I called his supervisor, and it was corrected very quickly.

CHAIRMAN CERQUEIRA: And two months later you got another inspection, right?

MR. WAGNER: Does our guidance filter down to the agreement States in regard to those issues?

MR. BROWN: There are several issues that are not covered by compatibility. Enforcement is an issue not covered by agency compatibility provisions. Some agreement States don't have formal enforcement programs, and so several things don't apply to agreement States.

The Inspector General world doesn't apply, and our conduct of employees may or may not apply, and enforcement does not apply.

MS. MCBURNEY: Under what is called the IMPAC review process, whereby the regions of NRC and the agreement States are reviewed on a periodic basis, some of the things that they look at are the enforcement, and how inspectors are conducted, and what sort of enforcement procedures are taking place.

And just coming from an agreement State, I would reiterate that an individual inspector cannot order someone to do that. If a facilitator is seeing that a specific licensing person is making undue requirements by unique licensing conditions -- we have a set of standard licensing conditions that are used that are very similar to NRC's.

But if you see that someone is putting that on the upper management would like to know about that, because we want more uniformity in licensing and I was

not aware of that situation. That is some of my people that you are talking about.

DR. VETTER: One last comment. I just wanted to say that I personally appreciate, and I am sure the entire committee appreciates, your invitation and openness to make suggestions about removing prescriptiveness in the regulations. Thank you.

MR. BROWN: And guidance especially. Guidance is more easily responded to than regulation, but I think I speak for John, and I hope that I speak for John in saying that we would certainly welcome both types of feedback.

DR. NAG: Under your new items, I had just one question basically.

MR. BROWN: Sure.

DR. NAG: More and more States are becoming agreement States. You know, once more than 90 percent are agreement States, how would the NRC and the ACMUI be supported? Do we get anything back from the States? Because from what I understand, ACMUI and the NRC are supported by the licensing monies of the institutions.

MR. HICKEY: And fines.

DR. NAG: If they go back to the States, do the States give something back to us for helping them do overall guidance and so forth?

CHAIRMAN CERQUEIRA: I have no idea. I defer to John on that.

MR. HICKEY: Well, I think I can answer that more generally. Right now the NRC funds the ACMUI. The States don't give the NRC money for anything, and as it should be.

And one of the things that we are looking at as a generic effort -- and I don't recall whether there was a report to the ACMUI in the last meeting, but we are looking at the impact of increases in a number of agreement States, and how that is going to impact NRC's role.

And that would be one of the things that we would have to look at, is whether the ACMUI should be more a committee that reports to the aggregate of NRC, and the agreement States, and their funding alternatives.

DR. NAG: Does the NRC get any funding directly from the government other than the institutions themselves?

MR. WILLIAMSON: Any general revenues come from the Federal Government to support NRC's oversight operations, independent of licensing fees.

CHAIRMAN CERQUEIRA: Do you pay your own way or are you subsidized?

MR. HICKEY: No. I understand that all of our money is recovered by licensees. However, we will still have reactor licensee fees. There are some charges that are moved because they are viewed as a general Federal interest, and like some universities are exempt from certain fees, and the reactors cover those fees.

So there are alternatives to getting the funding other than from the hospitals for this committee.

DR. NAG: Yes, but at this point thinking ahead, is this the time to ask the government or the Congress to appropriate some funding like from now? I mean, we could think ahead.

MR. WILLIAMSON: I think the ACMUI is a tiny, tiny, tiny percent.

DR. NAG: I am talking about the whole NRC and not just ACMUI.

MR. WILLIAMSON: Well, as more and more States become agreement States, where does the funding come to support this part of NRC. You shouldn't single out the ACMUI as sort of a tiny little bit of this. I think it should be structured in the way that is most effective.

CHAIRMAN CERQUEIRA: Exactly. But that is sort of a broader issue that really kind of exceeds the expertise of this committee, which is the medical use of

isotopes. So I vote that we go for the break here, and everybody be back at 3:15, and we will try and get done by 4:00.

(Whereupon, meeting was recessed at 2:58 p.m., and was resumed at 3:15 p.m.)

CHAIRMAN CERQUEIRA: All right. The first item of business is a visit from Mr. Don Cool, Dr. Don Cool, who is back, and he made one presentation, but now he has got to make another. Don.

DR. COOL: Thank you. This morning when I was here, before we started the meeting, and it seems like a long time ago because several other interesting things have happened upstairs of course in the meantime.

But before we started the meeting, John Graham and I were talking, and he had this peculiar smile on his face. And he was making very strange sort of noises about how this was his last meeting, and how much he was going to enjoy it, and about whether there was any implication of the fact that this time he was now seated next to Dr. Cerqueira, either to be kept in line or otherwise.

And in the back of my mind as he is saying all these things, I am thinking something is terribly wrong here, because either I have gotten more forgetful than I recognize that I have been getting, or there has

been some glitch in the process, because we always try to do some recognition and thanks to people who are rolling off the committee.

And no one had told me that dear John Graham was going off of the committee, and so I am going he has got to be pulling my leg, but I will just play along with this for some period of time.

And then we started the meeting, and had recognition of Dr. Naomi Alazraki. Well, a little bit later one of my staff people comes running into my office upstairs between meetings and says it true.

But in good true form we have scrambled around a little bit, and having validated that in fact John Graham is not pulling my leg, and that in fact this truly is apparently, unless of course we call a special session, and be careful.

MR. WAGNER: Hey, I'm here.

DR. COOL: You see what happens. And so I do want to take another opportunity both to apologize to John that I believed that you were pulling my leg for a good portion of the morning.

And to thank you for all of the efforts that you have given us, and that we do very, very much appreciate, and we also wish you the best. We know where

we are, and we can still find you, and we have been known to do that.

And we do in fact have a certificate that I would like to give you. I will also go ahead and admit on the public record that because Chairman Meserve is not in D.C., that we will have to pull it back so that we can get the proper signature affixed to the otherwise regularly printed materials in order for this to finally become a complete and legal document. But special recognition to John Graham and much thanks for his time with the ACMUI.

(Applause.)

MR. GRAHAM: I just told Dr. Nag that you wanted to make sure that I paid all my library fines before you really sign and send that document.

CHAIRMAN CERQUEIRA: While Angela is coming up, I would like to personally say that John has been on this committee way before I got on it, and he is a real clear thinker who really gets to the issues.

And we are really going to miss his ability to take a lot of the discussion and to come up with an appropriate motion. So he has been a very, very effective member of the committee, and I would like to personally thank him for all of his help.

The next couple of items will take very little time, and the first one is ACMUI interactions with staff, self-evaluation criteria for the ACMUI. And open discussion for the next meeting dates and agenda topics, and then I am supposed to summarize the meeting, which this time will not be as hard as it has been in the past.

And while we are waiting for Angela, the first thing is really the interactions with staff, and we really do need her. If we go to the next tab, it is ACMUI self-evaluation criteria, and this is something that we are supposed to do on a periodic basis to make certain that we are still meeting the needs of the NRC, and that we are squandering their money foolishly on lavish parties, and to come up with other ways that the NRC can support the efforts.

Maybe we could go through and look at these questions and see if they need to be changed, in terms of the self-evaluation criteria. Does the staff and the ACMUI interact in such a manner as to satisfactorily address issues before the Committee.

MS. MCBURNEY: Are we just evaluating the questions or the responses?

CHAIRMAN CERQUEIRA: Do we have responses? Yes.

MS. MCBURNEY: The responses from last year's.

CHAIRMAN CERQUEIRA: Yes, I guess we are supposed to do it. It looks like we met the self-evaluation criteria.

MR. WILLIAMSON: I think the communication is quite good, and they have been I think improving on their feedback and giving us follow-up of specific recommendations.

And maybe we ought to consider when we really have a concern about something to make sure in the future that we always put it in the form of an action item.

CHAIRMAN CERQUEIRA: I think so. Again, an action item or a motion that basically can be clearly identified. I think we need to get some feedback from them as well. You know, the interaction should be both ways.

We should get back some information, like with some of the issues that we discussed today about the board approval process. There is sort of a mine field in a lot of ways, and I think we can give them some useful input provided that we have the information available that is before them. Dr. Nag.

DR. NAG: When you are talking about both ways, I am wondering can the NRC staff give some feedback to us about whether we are doing a good job, and whether we are giving them the information that they want, and that would be helpful to us so we know how or what to do, and how to prepare the next time.

DR. DIAMOND: It would be along those lines that I would like to have feedback to know how effective we are in communicating our intents to the Commissioners. I think a lot of time we spend trying to provide intent and context to some of our discussions, and I would like to know if what we are doing is effective or not.

MR. WILLIAMSON: And I think a follow-up to that comment would be -- and which I fully agree with -- is that we are not a commission level advisory committee. We report to the Director, Don Cool, basically. That is the sort of level that we report to.

And I noticed on page 4 of our bylaws or charter, or whatever it is, that we are supposed to have an annual briefing in front of the Commission as a group, which says it is in the spring, and to my knowledge we have not had that this year.

CHAIRMAN CERQUEIRA: We have not had it this year. There was some discussion earlier between myself and staff, and since we didn't know the status of Part

35, and there really had not been any other issues in terms of updating, we could request that it be done in the fall.

MR. WILLIAMSON: I think we should. I would really like to myself bring to their attention this issue of board certification, and the importance and difficulty of the rule text, in terms of its practical implementation.

I think it is very important and I would urge us to make use of that expectation, because that was put into -- you know, this was made up about five years ago when I first joined this group.

CHAIRMAN CERQUEIRA: Right.

MR. WILLIAMSON: And it was basically just because of this complaint that we were not a commission level advisory committee that this was put in as a sort of safeguard to make sure that there is some mechanism for directly getting the Commissioner's ear.

DR. NAG: And if we are having a fall meeting and we are having it with the Commissioners, then I think it should be a two day meeting so that one day we have a regular meeting and one day with the Commissioners.

CHAIRMAN CERQUEIRA: So, John, I guess you are hearing the input and to basically for the November

meeting to have a briefing to the Commissioners on some of the items that we think are important. Okay. Those are very good comments.

Number Two. Do the committee members clearly define issues for the staff and provide timely, useful objective information to the staff when requested. I think that the answer to this is yes.

I think the E-mail option works very well and I think Angela has been using that a little bit more than past staff members, but I certainly think that other members of the staff could communicate with us that way in a timely fashion.

I mean, a lot of the other organizations that I take part in, we even do votes over E-mail, and so I think that is something that should be utilized. Any other comments? Dr. Nag.

DR. NAG: Yes. On that same thought of using E-mail, the other thing that I think the Commission or the NRC would think about is that it i sometimes hard to hold the principal meeting. But if we need to hold a quick meeting and we have a mechanism to hold a teleconference call, and have it in lieu of a meeting.

You know, sometimes you may have one item that takes one hour and we don't need to have a physical meeting for that.

CHAIRMAN CERQUEIRA: I think that is a good point, especially some of these ideas, in terms of a subcommittee that would be addressing specific issues. That is something that could be very easily handled in that way. John.

MR. GRAHAM: I would recommend that to the Office of the General Counsel. We have discussed that in the past, and the difficulty is to comply with the threshold for a public meeting of the Federal Government, and to do it over an internet forum.

DR. DIAMOND: So maybe that would be best confined to any subcommittee work that we might do.

MR. GRAHAM: Yes.

MR. WILLIAMSON: Even with subcommittee meetings, you can't do it. I would also say that for a large group like this, with more than 5 or 6 people, I think it is pretty tough to have a productive conference call.

DR. DIAMOND: On that same issue, as far as efficiency, perhaps we could also go -- instead of Angela having to send us the big binder full of the minutes from each meeting, perhaps we can have an option of just accessing that on line as well, and save some trees.

CHAIRMAN CERQUEIRA: I think that is a good idea. We have killed quite a few trees at this meeting as well.

DR. DIAMOND: We did pretty good today.

MR. WILLIAMSON: Yes, it is quite slender.

MR. WAGNER: I notice that they took to heart my recommendation that the multiple slides be put on each page.

DR. DIAMOND: That's right.

CHAIRMAN CERQUEIRA: Okay. Any other comments?

MS. HOBSON: On the public meeting issue, in California, we handle that by actually noticing meetings and giving the public a telephone number that they can call and they can be at least listening in on the conference call.

CHAIRMAN CERQUEIRA: That's a possibility. I am on a HFCA committee, and basically anytime that you get more than three people together, it constitutes a public meeting, and you need to have Federal Register notice and everything else.

Well, I think that is something to consider. The committee is quite flexible in working with some of these issues. There are regulations that prohibit some

sort or types of interactions, and we should work on that.

So, Angela, maybe we can give this back to you. We kind of leaped ahead a little bit in the earlier sections.

MR. WILLIAMSON: We are starting the self-evaluation.

MS. WILLIAMSON: Okay.

CHAIRMAN CERQUEIRA: Maybe you can go to that.

MS. WILLIAMSON: Well, I will try and make this very quick. It is not that complicated. There has just been a couple of changes, and not anything monumental. But one of our recent procedural changes as you are all actually aware of is the fact that we now for the recommendations in the past, that maybe they didn't get addressed in the most prompt manner.

Well, what we are doing now is we having the IMNS division director -- Don is answering those questions, and we are forwarding our stance on the issues that have been raised, and the recommendations that have been raised. We are forwarding those directly to you as we did before this meeting today.

And we would ask you that if you prefer the briefing book in advance to go over it, or you would just

rather wait until you got here to get it. The good thing about seeing it in advance is that you do get the chance to read through things, and the downside though is that when things change, it is not always feasible or easy to -- we don't want to provide you with 17 revisions. So that is the downside.

CHAIRMAN CERQUEIRA: Jeff.

MR. WILLIAMSON: Yes, I have a similar problem with a large committee that I run in the AAPM. We have gone to a website based directorate, and we put all the hundreds of pages on there, and then revisions can be slipped in and out easily, and they are all in the formats so that people can download them, and print them out, or whatever they want to do. Is that a possibility, that you could put it on a secure website for us to look at as PDF documents?

MS. WILLIAMSON: Yes, that is a possibility. We are at the current moment developing an ACMUI website. So that is on our to do list.

MR. WILLIAMSON: And then people could have a range of options to access the material and what form you put it in.

MS. WILLIAMSON: Okay. And the travel voucher procedures, along with the professional voucher procedures. We all know that there are issues with those

things. So we are going to very briefly go over those issues.

The thing that I would like to do a little bit differently -- and I know that it is not necessarily going to work perfectly, but what I would like to do is -- my overall vision is to not let anyone walk out with anything unless there is no way around it.

Because in the past it seems that the most challenging and most difficult thing to do sometimes is to get signatures. So if we can get the paperwork filled out to the extent possible before people leave, and get the paperwork signed, and just leave it, then that is going to alleviate a lot of the issues that we have of getting people paid promptly.

Another issue that I want to point out is the Federal Government does not like to issue checks. It is going to save us both a lot of frustration if you go on ahead and fill out the direct deposit forms, and unless it is a one time only payment, the Federal Government does not want to issue you a check.

So please, if you have not done that, take care of that. I have passed out direct deposit forms. If you don't need to fill out the form, just ignore it. But if you do, please do that so that we can this into our payroll center and get you paid.

MS. MCBURNEY: If that was done in the past do we have to repeat it?

MS. WILLIAMSON: No, you don't have to repeat it. Regardless of the type of payment, the government does not want to give you a check for it.

MR. WILLIAMSON: How can we fill out the travel voucher if we don't know what all the expenses are going to be? How can we do that in advance?

MS. WILLIAMSON: My proposal is that you leave the paperwork here and just forward to me whatever the fees you might have had are. We don't need a receipt unless the expense is over $75. We need the original hotel receipts, and we need the receipts for expenses over $75.

DR. NAG: So, $75 for all the expenses or $75 per expense?

MS. WILLIAMSON: Per expense.

MR. WILLIAMSON: So do you just want us to sign the complicated form that none of us know how to fill out in advance and leave it with you, and then take the simple form home with us, and then after we know what the amounts are, fill it in and send it back to you?

MS. WILLIAMSON: You can fax it to me.

MR. WILLIAMSON: So you just want us to sign the NRC Form 6041 in advance; whereas, in the past, we

were filling out the work sheet and then you would send us back a filled out voucher, and we would sign that and send it back to you.

MS. WILLIAMSON: Right.

MR. WILLIAMSON: So that we are trying to eliminate that additional step?

MS. WILLIAMSON: Right. This is just a proposal, and it might just work out very well.

MR. WAGNER: On the voucher for professional services, I guess there is some confusion. My understanding is that it starts from your time of travel, and it includes your travel, as well as your time here.

MS. WILLIAMSON: Yes, it does.

MR. WILLIAMSON: And isn't there a rule that if it is more than 5 or 6 hours in one day that you are supposed to charge the whole day; is that right?

MS. WILLIAMSON: Right. Over 6 hours, you get the full days pay. If it is less than 6 hours, then you get the hourly rate. Also on your professional voucher, there is a contract number.

This form that was actually filled out for you when you were brought on to the committee, it has a contract number on it, it is very helpful if you can put that number on the professional voucher.

(Multiple discussions off the record.)

CHAIRMAN CERQUEIRA: All right. Moving right along. Let's go to the self-evaluation. Angela, we had already started that, and gone through a couple of the things. What else would you like us to do with that?

MS. WILLIAMSON: Well, there is really -- I just revised the last one so that you basically know what you said the last time, and maybe it would help you formulate things that you would have forgotten. I don't really have a whole lot of input into the self-evaluation.

CHAIRMAN CERQUEIRA: I guess my question is are we supposed to do another self-evaluation?

MS. WILLIAMSON: Yes.

CHAIRMAN CERQUEIRA: >From this meeting, as opposed to --

MS. WILLIAMSON: Yes, we are due a self-evaluation from the committee.

MR. WAGNER: I think it should be pointed out that --

MS. WILLIAMSON: There was a meeting in November.

MR. WAGNER: -- there was a commission briefing wasn't it?

MS. WILLIAMSON: No, a regular meeting.

MR. WAGNER: There was no spring meeting.

CHAIRMAN CERQUEIRA: I think there was a spring meeting actually.

(Multiple discussions off the record.)

MR. WILLIAMSON: I think to go back in time, before Barry Siegel was Chairman, where this committee was very more of a -- and so I think that the committee as a whole should be proactive and stay in the process and keep the meetings.

I don't think we should compress the format if we have any choice about it, because over the years my observations have been that this committee has been an extremely effective instrument, at least at the level of small detail, and has had an important influence on the outcome of a number of regulatory meetings.

DR. NAG: Well, do we have to write something and send it to you right now or what?

MS. WILLIAMSON: No.

CHAIRMAN CERQUEIRA: Well, we have several options, but obviously we are to do a self-evaluation, which would consist of people looking at these questions and sort of addressing with several sentences at least, and what I could do if people are willing to do that and send it to me via E-mail preferably, I could then take it as an attachment and take the information and try and come up with some generalizations.

So if people could do that and maybe within two weeks send me written comments on their self-evaluation of the committee, answers to these 10 questions, and send me comments about these specific items it would be very worthwhile.

The best way to do it is to send it as an E-mail attachment, and preferably in Word, and then I can paste it and bind it, and that should work.

DR. VETTER: Can I ask a question? On Item 6, do committee members bring issues, et cetera. Do members of ACMUI actually solicit from your colleagues comments or issues that they would like you to bring to the Commission?

CHAIRMAN CERQUEIRA: Speaking for myself and the nuclear cardiology community, I do get input from the ASNC, the American Society of Nuclear Cardiology, on some of those issues.

DR. VETTER: So you get that because they know that you are on the committee?

CHAIRMAN CERQUEIRA: Yes.

(Multiple discussions off the record.)

DR. ALAZRAKI: There is another side to this because I know that Barry Siegel, when he was on, was very careful not to be influenced by so to speak constituents, and to try not to be sort of a lobbyist

type of relationship to the NRC, and I think there is a lot of merit to that thinking.

On the other hand, you are representing the groups, and so I think it is a tough position, and we should all be on the same page.

MR. WILLIAMSON: Well, I think it is very clear that we are consultants, and we are paid by virtue of our personal and professional expertise, and we are supposed to speak our own minds, and to collect information. But not to represent constituents.

CHAIRMAN CERQUEIRA: And I think there is a fair amount of compromise that we all do with this committee and during discussions, and so I think it is important to know what our constituents represent, and we will obviously make decisions that are independent of that.

MS. MCBURNEY: I think it is good to know what they feel the issues are, but not necessarily to mirror the entire or what the majority of them think about particular issues, but certainly we could bring forth issues that are important, but not necessarily take a position on those as reflected by that group.

DR. NAG: I see myself as a consultant to the ACMUI, or to the NRC based on my professional expertise. If they want an input of the radiation

oncology societies -- ASTRO or ARC -- they have sent their own particular representatives.

So I think I speak for myself and not necessarily for anyone else, although they may send me a message pertaining to medicine or in the oncology sense, but that's it. I don't speak for them.

CHAIRMAN CERQUEIRA: Well, I guess getting back to the self-evaluation, should we be actively soliciting issues from our constituents.

DR. DIAMOND: What I do is that a week or two before the meeting, I make some calls around and what I try and do is not just contact members of the leadership of the different professional societies, but just call up a lot of people that I know that are not particularly active in the leadership just to get a sense of how they feel as practicing physicians, with the rationale that if I don't ask for their opinion, I am not going to know what they are thinking.

MR. WAGNER: I think I just brought up two issues today which were generated out of my communications with other RSOs, and also other communications that came to me from other sources. I don't think we have to be afraid about whether or not the issues are representative of the specific constituency.

I think that the discussions that go on at this table are clearly open and I think they are extremely healthy, and relatively unbiased with regard to the nature in which they are presented. They are presenting the position of the person who is assigned to represent, such as myself with nuclear physicists, and Jeff with medical physicists, and we are representing our group as a whole, and trying to stand up for it, and being considerate of everybody else. I think we do a great job.

CHAIRMAN CERQUEIRA: All right. Have we set a date for the next meeting?

MR. HICKEY: We have not done that yet.

CHAIRMAN CERQUEIRA: Well, if we could solicit agenda items say probably after the Labor Day weekend in September, then we could have specific information for you for the agenda, and we should have a meeting in November, and at that point try to brief the Commissioners on what is going on with the Committee.

(Multi-discussions off the record on dates.)

CHAIRMAN CERQUEIRA: All right. So the 24th and 25th of October tentatively.

MR. HICKEY: We will target that date, and we won't be able to confirm the Commission schedule this

far in advance, but we can tentatively target that week and see what we can work out.

CHAIRMAN CERQUEIRA: So we have set the next meeting date, and the agenda items we will solicit from committee members, and we will solicit in the early part of September, and plan for the meeting in the next to last week of October.

So I think we are down to the last item which is the summary of the meeting.

MR. HICKEY: Mr. Chairman, could I raise a point of order back on this self-evaluation. I know -- and I think it is in your book, but the committee did submit a self-evaluation in June, which has been less than a year.

So from the point of view of efficiency, if there is a perceived issue on how much effort and how productive it is going to be to do another submittal, first of all, you could do an evaluation in the context of the other evaluations, and what do you have that is already not stated in the previous evaluations.

Or we could check to see if anything is necessary at all. I was already hearing some comments from the committee members, but --

CHAIRMAN CERQUEIRA: Well, part of the reason in doing the self-evaluation is to give the

Commissioners the feeling that this committee is doing something and its real goal and function is being met.

MR. HICKEY: And I would just draw the committee's attention to the evaluation that was already done, and there is no point in repeating things that were already stated in the previous evaluation.

MR. WILLIAMSON: Well, it is supposed to be done every year, and I think the reason that it is here is because June will be upon us well before the next meeting.

MR. HICKEY: Yes.

MR. WILLIAMSON: And so there needs to be feedback from the group,a nd I do think there are some suggestions that are in there, including -- and most of the suggestions don't really conform to the questions that were asked.

CHAIRMAN CERQUEIRA: Why don't we plan on getting people's input in the next two weeks then. How about by May 2nd. And so to summarize the meeting, we gave awards to Naomi and to John Graham for their service to the committee, and they both did a superb job and I hate to see them go.

We had the first line follow-up on items from the previous meeting. I think this time that we did get more feedback and we spent a lot of time on some of

these issues, and had a lot of discussion, and I think we all feel better on the feedback that we did receive.

And the status of the vacancies, I think what has been alluded to by Jeff, we need to be more efficient, and we had meetings where we had very few voting members.

And so I think that the process -- there is obviously a procedure that needs to be initiated as to the NRC staff level, and it sounds like they have a 3 person committee waiting to identify that outside Federal employee consultant and give them the input.

And once the notice goes out in the Federal Register, within 60 days, by the time we get all the recommendations, and by the end of the last week of that 60 day deadline, we should have a decision.

So, Angela, if you could maybe follow up on that, and identify the time lines, and just kind of notify either the whole committee or myself who are the NRC staff people and the outside consultants. And as to Naomi's recommendation as to her screening the recommendations for her replacement, I think we should take her up on that.

We heard from Cathy on the on the Part 35 rulemakings and sort of identified the best case scenarios of the publication in June, and implementation

on January 1st, 2002. That the OMB has some issues, and that at most two months. It looks like the NRC has looked at the recommendations, and has decided that the process was too late and that same position has been sent to the OMG, and we have no idea how they will react as to that, and we will have to see.

Transition implementation issues, and I don't think there is much there, and the recognition of certification boards. In talking to some of the committee members during the breaks, this is an area where all of us feel uncomfortable. We feel that this is an important process and we all agree that the NRC should not be -- the practice of medicine.

And that we need to make certain that the eligibility requirements for some of these boards meet the requirements, and we have physicists, radiochemists, RSOs, authorized users, and we have all these different levels of radiation instances, and then all of a sudden we have gotten boards from Europe, and we have no idea what the requirements are in some of these boards, and what passing boards really means there.

So I think this is something that is going to require quite a bit of attention of the committee, and realistically if we meet that January 1st, 2002 deadline,

all of that will need to be in place by then, and so we don't have a lot of time.

We had a lot of discussion on brachytherapy procedures not covered by the FDA approval, and I think it was the uniform consensus of the committee members and the FDA representative, and the NRC, that our issue is radiation safety, and what physicians do should be -- that the NRC should really deal with radiation safety and not the practice of medicine. Jeff.

MR. WILLIAMSON: With all due respect, Mr. Chairman, I would like to remind you that under the sort of issue of board recognition, there was a strong recommendation to the staff that they involve appropriate ACMUI members in the discussion of implementation criteria for the current rule text for those areas where it appears that the board certification system has broken down.

CHAIRMAN CERQUEIRA: Thank you. The next item was the physical presence issue for the new brachytherapy procedures, and there was a lot of discussion and I think the committee in general felt that the standard is a 3 or 4 person involvement, but given some of the issues that were brought up, everybody felt trying to come up with creative ways of deciding if the

alternate people be physically present should be explored.

And the broad licensees to utilize new brachytherapy procedures, and that the committee discussed that basically for broad scope licensees that should be left to the institutions to basically make decisions and that non-broad scope licensee sites need to go through an application process.

And then the rejection of medical waste by local landfills. We didn't really take a vote, but we felt that the offender or the person who was involved in disposing inappropriately radioactive material should have some financial liability for their actions, and we talked about costs associated with --

MR. WAGNER: Well, that is not the NRC's position to do that. The idea was that the best thing to do was to make sure that the facilities avoid from the costs from the waste companies, who will charge them for returning the waste, by installing detectors at your exit sites so that you don't accidentally ship something out, whether or not it is appropriate to ship it out or not, and that is regardless of the question. The question is you should bring it back and not ship it at all.

MS. HOBSON: But didn't we decide to ask the NRC to send out some kind of advisory notice recommending that to --

MR. WAGNER: Yes, that they ought to consider the idea of notifying licensees that this is a potential solution to avoid those kinds of charges.

CHAIRMAN CERQUEIRA: That is pretty much the discussion. I would like to thank Angela for dealing with this travel issue, the voucher and everything else. That's great. I hope it will work, and everybody will be compensated. Lou.

MR. WAGNER: You did miss the fact that two issues were brought up new from the committee.

CHAIRMAN CERQUEIRA: Yes, I did. I apologize for that. Lou brought up two items that will be addressed by the staff. Anything else?

MR. HICKEY: No, I don't have any program items, but again I wanted to thank everybody for their time, and particularly for the people where this is their last meeting -- Lou Wagner, and John, I think already got away, and Dr. Alazraki, perhaps we will see you again in other contexts.

But we recognize that you all have busy schedules, and this is a collateral duty in addition to your full-time positions, and you have other collateral

duties, and so thank you very much. It gives us a different perspective that we don't get and we don't have if we don't have physicians on the staff. So thank you very much, and thank you for bearing with us.

CHAIRMAN CERQUEIRA: The meeting will now be adjourned.

(Whereupon, the meeting was concluded at 4:13 p.m.)

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