Official Transcript of Proceedings

NUCLEAR REGULATORY COMMISSION

Title: Advisory Committee on the Medical Uses of Isotopes: Teleconference

Docket Number: Not applicable

Location: Rockville, Maryland

Date: Monday, July 21, 2008

Work Order No.: NRC-2340 Pages 1-105

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NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

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MEETING

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TELECONFERENCE

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MONDAY,

JULY 21, 2008

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The committee met at 1:00 p.m. via teleconference based in Rockville, Maryland, Leon S. Malmud, Chairman, presiding.

COMMITTEE MEMBERS PRESENT:

LEON S. MALMUD, M.D., Chairman

RICHARD J. VETTER, Ph.D., Vice Chairman

DOUGLAS F. EGGLI, M.D., Member

DARREL R. FISHER, Ph.D., Member

DEBBIE B. GILLEY, Member

RALPH P. LIETO, Member

STEVEN R. MATTMULLER, Member

SUBIR NAG, M.D., Member

SALLY SCHWARZ, Member

BRUCE R. THOMADSEN, Ph.D., Member

WILLIAM A. VAN DECKER, M.D., Member

JAMES S. WELSH, M.D., Member

COMMITTEE MEMBERS NOT PRESENT:

ORHAN H. SULEIMAN, Ph.D., Member

NRC STAFF PRESENT:

Jacqueline "Jackie" D. Cook

Christian "Chris" E. Einberg

Cynthia "Cindy" M. Flannery

Sandra "Sandy" L. Gabriel

Donna-Beth Howe, Ph.D.

Penny A. Lanzisera

Sophie Le

Robert “Rob” J. Lewis

Edward “Ed” M. Lohr

John R. Madera

Alexis Sotomayor-Rivera

Ashley M. Tull

Duane E. White

Jackie “Jack” E. Whitten

Ronald “Ron” E. Zelac

ALSO PRESENT:

Dean Broga

Tom Burnett, MDS Nordion

Ann Warbick Cerone, MDS Nordion

Brian Erasmus, MDS Nordion

Sandor Erdelyi, SIRTEX

Lynne Fairobent, AAPM

Emily Gardner, ASNC

Melissa Martin, AAPM

Richard Martin, ASTRO

Jacob Ninni, RSO, Rhode Island Hospital

Mike Peters, ACR

Doug Pfeiffer

Amanda Potter, AAPM

Riad Salem, MDS Nordion

Ken Thurston, SIRTEX

Cindy Tomlinson, SNM

Gerald White, AAPM

P R O C E E D I N G S

MR. EINBERG: Very well. Thank you. It's Chris Einberg. Dr. Richard Vetter will conduct today's meeting. Following a discussion of each agenda item, the Chair, at his option, or the Vice-Chair, at his option, may entertain comments or

questions from members of the public who are participating with us today.

At this point, I will turn the meeting over to Robert Lewis, who is the director of the Division of Material Safety and State Agreements, who has some opening comments that he'd like to make.

MR. LEWIS: Thank you, Chris. Good afternoon, everyone. I apologize for the mix-up we've just been experiencing, and I'm very appreciative of your patience, and the hard work that the people here have been doing to scramble, to get this up and running.

First of all, I want to thank ACMUI for your time. Your input is very valuable to NRC. The issues we have before us today are particular issues we need your guidance on.

Before I get too far along, though, I did want to introduce Chris Einberg who has been leading the meeting so far. So it's a little awkward for me to introduce him, frankly, but the FACA rules are as they are, and as the federal official here to kick off the meeting. But Chris is our new branch chief for Material Safety and State Agreements Division, Medical Safety and Events Branch, and he will be from this point forward the Designated Federal Official for the

ACMUI. And this is his first meeting, I believe, so--Chris came to us from our Sealed Source Safety and Security Branch where he was the architect of our NRC fingerprinting requirements over the last couple years, and came to us from DOE before that.

So turning to the goals for this meeting, we have three issues on our agenda. Discuss issues with permanent implant brachytherapy rulemaking. That's currently before the Commission.

I had hoped that we'd be at a point where we had gotten the Commission requirements memo for that rulemaking but they haven't provided that to us yet. But I think that all the issues to discuss there are out in the public, so perhaps we can revisit that when the requirements memo is issued, as needed. But I think we can still have some progress today on that topic.

The second major area is to assess path forward or developing technical basis information. NRC needs help on determining a technical basis for our response to the AAPM and Ritenour--the Ritenour petition from--when we deliver a rulemaking to the rulemaking group, we have to have a technical basis from which--and that includes impacts, regulatory or technical impacts of the rule, economic impacts, and

that provides the basis from which the proposed rule is drafted, if the petition is accepted.

And finally, we want to discuss issues supervising the work experience cases for Yttrium-90 microspheres. This was a topic at our last meeting, and I think this is follow-on discussions on that topic.

Before we get into those three areas for this meeting, this is my opportunity to lay out some of the current projects of interest to ACMUI that we have here, and that'll be occurring over the next few months.

Is everyone else getting a lot of feedback on the phone?

MR. EINBERG: Occasional.

MR. LEWIS: Yes. There's something going on there. When you're not speaking, if you do have a mute button, if you could use the mute button, it might help the meeting attendees.

We have received a letter--we sent a letter--I'm sorry--to the American College of Radiography--Radiology, on June 4th, 2008.

In that letter, we asked the ACR to select an individual to attend some of the ACMUI meetings as a non-ACMUI member. And if the meeting agenda had a

particularly area of interest to ACR, we would use the ACR representative in a technical consultative role to the committee, and in moving forward we'll look for the ACMUI Chair and the NRC management to identify which agenda items we need to involve the diagnostic radiologists, moving forward.

On the cesium chloride issue with blood irradiators, this is coming out of the National Academy of Sciences study from February, where they recommended phasing it out, phasing out self-contained irradiators containing cesium chloride sources, which are used to, in the medical industry at least, in blood irradiation and research.

And the committee had been tasked by the Commission to develop a study regarding the efficacy of cesium chloride irradiation versus x-ray irradiation. And in that regard the NRC staff has done some work with our technical library in a literature search, and I'll look to discuss with the committee at some point--or the subcommittee members that are working on that, we can provide the literature search info we have, so that you guys can be best-positioned to get off and running on the project that you owe to the Commission.

The ACMUI comments on fingerprinting. We

did receive comments from ACMUI on fingerprinting and draft. I guess we're looking for the final comments and we will be providing those comments to the Commission, as directed.

On another topic, we did publish a **Federal Register** notice on May 21st, since the last meeting, which was the response to a petition for rulemaking from Peter Crane on Iodine-131 patient release.

There has been a lot of interest in the press, and from members of the public, about what that petition and the resolution of it actually means, and the guidance we issued coincident with the petition determination.

And finally, as I mentioned when I started, the proposed rule on permanent implant brachytherapy is still not published. that should be coming soon and so today's topic is very timely.

Again, thank you for your time. At this point, unless the ACMUI members want to ask me any questions, I'll turn the meeting over to Dr. Vetter.

DR. VETTER: Okay. Thank you, Mr. Lewis, for those opening comments. We do, as you mentioned, for ACMUI members, and members of the public, we do have three items on the agenda. Part 35 Rulemaking on Permanent Implant Brachytherapy; a Technical Basis to

Support the Rulemaking for the Ritenour Petition; and the Y-90 Microspheres Guidance. We'll take those in order.

First of all, is there any other background material, or more direct phrasing of the question you're looking for on each of those items as we take them? Number one, Part 35 rulemaking.

Mr. Lewis or Mr. Einberg or Ms. Flannery, any specific questions you would like for the committee to address.

MS. TULL: Dr. Vetter, this is Ashley Tull. I think Dr. Nag had some concerns with the rulemaking, and so this was just his opportunity to bring those issues up with the committee, so you could have a discussion and provide any recommendations to NRC.

DR. NAG: Do you want me to outline my concern at this point, or what do you want me to do?

DR. VETTER: Yes, Dr. Nag, if you would outline your concerns at this point.

DR. NAG: Okay. This is Dr. Nag. I was one of the members of the ACMUI subcommittee. In fact, there were two major people, myself and one of the physicists, that made the original recommendations that went to the NRC official, and then from there

went to the rulemaking section.

But that did not come back through either the ACMUI or the subcommittee. So I feel that there may be some areas where it is arbitrary or ambiguous, or, you know, that can lead to problems. And I would like to specifically refer those of you who have your handout, to refer to the next-to-the-last page, which is page 33, wherein it says that--do you all have the rulemaking issue handout?

Page 32. Well, this is a directive, and it says Report and Notification of Medical Event. There, when it goes to say the total--the 20 percent--there's a 3 centimeter rule, that if it's more than 3 centimeters. It is true that during our discussion, we said that usually we do not plan to have any seeds that can be more than 3 centimeters away from our implant site.

However, the way this has been interpreted and written into the regulation is that even if one seed were to be outside that 3 centimeters, it would constitute a Medical Event. I have discussed this with many of my clinical colleagues, and we all agree that even in the normal course of the regular implant, there are certain reasons why a few seeds can go outside that 3 cm, and it's not something of medical

concern, although it uncalled--I mean unplanned for.

For example, if, when you're pulling the needle out, you can sometimes suck one or two seeds down, and it may be more than 3 cm away.

Secondly, when we place the seeds, some seeds can go into the adjacent like threshold and from that, A, either migrate to the lung, in which case it does not function as a Medical Event, because it is very well-recognized that that is a migration or embolism.

However, a few seeds can also be embolized into a pelvic-like vessel, in which case it may be only three or four centimeters away, and there's no way of knowing whether that would be an embolized seed, or it be a seed that was recently placed there.

The only thing, we would know is after the implant, when we take a CT or x-ray, we will see a seed 3, 4 cm away, and that would be considered a Medical Event when it's not.

So these factors sort of are very concerning to the clinicians in these new implants, who have done literally thousand of implants, and when we--if we look back and we look at every one of them, there will be a few of these cases, which has not caused any adverse event. And we recognize that these

things do happen.

So I think that when we mentioned--normally, we don't have seeds that are 3 cm away. In the normal course of events, a few, you know, do happen, but it's not what normally happens, and that was not properly recognized by the rulemaking section.

And the other comment we have is that we discuss and make some recommendations at the ACMUI level, that goes to the NRC official, and then from there goes to a different section of the NRC, the rulemaking group, which had not heard many of the discussions that had gone on in the ACMUI, and is only relying on the last few set of summary recommendations, without going through all the discussions that they've had, and as part of a long-term thing, I think if NRC is doing any rulemaking based on recommendations from ACMUI, I would like to recommend that they come back to the ACMUI, get a brief look-over, to see whether that is what we actually meant.

So that's the major problem that, or major concern we have, all the clinicians have, and the problem, or the worry is that if this is allowed to be enforced into rule, we will be having a lot of Medical Events, or so-called Medical Events that are not

really Medical Events, and many clinicians may not even risk to continue doing permanent implants under fear that, you know, if one seed goes out more than 3 cm away, it will be called a Medical Event, even though it's not a problem. When it were a Medical Event, it would force it. It means a lot of work for the entire department and entire university, to even justify what has happened.

So I think this is, you know, the major reason why, you know, I wanted to have it discussed.

The second reason is there is, on the second part saying 20 percent beyond the treatment area. Now it depends how the NRC official will interpret the treatment area, because you do want to allow for seeds in the planning process to be beyond the treatment organ, and that would still be a correct placement. So we feel that there, again, there is some ambiguity as to what the official will call as the treatment organ.

And the third thing was also mentioned in the subcommittee but not recognized in the final rulemaking process, and that is we had mentioned that many of the permanent implants are done in prostate, and many of the recommendations we had made were for the prostate.

However, anything that is, any rule that is done for a permanent implant will apply to all permanent implants, not just to the prostate, and when it applies to other organs, we have said that, for example, most operations in brachytherapy are with human heads, there are no well-encapsulated or regularly visible target volumes that can be used to precisely determine whether the implant is a treatment site accuracy Medical Event.

In such cases, only grossly erroneous Medical Events can be determined with certainty. NRC enforcement policy must be based upon realistic expectations of the precision that can be achieved in the Medical Event determination in different clinical settings.

So this uncertainty in non-prostate permanent implant is also not being carried on, and again, we are afraid that the interpretation may be such that, while they say that this is more than 3 cm away, or more than 20 percent are in the area, in the adjacent area less than 3 cm away. So I think those were the major things that we had problems with. We did discuss this at the ASTRO telephone conference call with a few other clinicians and a few other witnesses

DR. VETTER: Okay. Thank you, Dr. Nag.

This is Dick Vetter. At least two members of the committee did respond with comments that they shared with everyone. That was Dr. Thomadsen and Dr. Mattmuller. Would either of you have any comments on this issue at this time?

DR. THOMADSEN: This is Thomadsen, and I think that Dr. Nag summarized our concerns very well.

DR. NAG: And I think Dr. Welsh may want to mention something because he's the other clinician who is on the telephone conference call, who is doing, you know, the permanent implant.

DR. WELSH: This is Dr. Welsh here, and at this point I agree that Dr. Nag has summarized out points very helpfully.

DR. VETTER: Steve Mattmuller, any comments?

[No response]

DR. VETTER: Okay. Are there comments by any other members of ACMUI?

MR. LIETO: This is Ralph Lieto. I have a question for NRC staff, cause I'm not quite sure what Dr. Nag is proposing at this point, but the document that went out to us with the proposed regulations that went to the Commission, it was my impression from the

cover letter that there wasn't really anything we can do until this comes out as a publication for the **Federal Register**. Is that an accurate assumption on my part? This is--that's directed to NRC staff.

MR. LEWIS: This is Rob Lewis. Let me address a couple of points and then I think some of the NRC staff might want to elaborate. But in terms of the rulemaking group, and the medical safety group not collaborating, I think that our process made sure that the views are collected. The rules are all done by a working group, which includes the NRC programmatic staff, which is my staff, the rulemaking experts, which is in DILR, it's a sister division under Charlie Miller, and the regional and state expertise as well.

And so the views that are provided to the committee, it may be true that the rulemaking experts don't attend the entire committee meeting, but our process should guarantee that the views of the committee, when they're given to the subject matter experts, get back to that working group.

And then overseeing the working group's effort, most rules, many rules have a steering committee made up of managers, and I would be on that steering committee as well as Dennis Rathbun, the

rulemaking division director and a regional director.

So our process is set up to ensure that the views of the ACMUI are considered as the working group develops the Commission paper with the proposed rule.

Now the process is as it is. It seems like in this case, that you, at least, believe that that didn't happen, so--

DR. NAG: Well, no, what I'm saying is the rulemaking was based primarily on the recommendations of the ACMUI. Everywhere it says as per ACMUI we did this, as per ACMUI we did this.

But once that was drafted, it never came back to the ACMUI to say, "Is this what you meant?" And if it had, I would have been able, or the ACMUI would have been able to say yes, or no, or we meant this but, you know, not this. So I think that would have been helpful and we would not be in this quandary that we are now, that the rulemaking has been done, do we now step back, change the whole thing, or, you know, what do we do?

MR. LEWIS: I understand that point. So the process, going forward, can take one of several paths. One of the easiest paths would be for the--to be considered comments by the ACMUI as part of the

public comment process of the proposed rulemaking. Will they be submitted on the docket? They be required to be responded to. And so would all the other comments that go with it. And that's actually why we do propose rules, to get the comments from people. Sometimes people have been involve din the rule, and we put out the proposed rule, and say this is what we thought you mean, is this what you really meant?

That's very common in a proposed rule.

Also, you know, some aspects of your comment were kind of one-size-doesn't-fit-all kind a comments, and those are exactly why we do propose a rule, because of the broad spectrum of uses and materials.

So one path would be for comments by the committee on the proposed rule, when the Commission approves, assuming the Commission approves to issue a proposed rule.

If you feel, however, that the Commission was given incorrect information, and that's the committee's judgment call to decide that, you know, then we have other things to get information to the committee as they vote, to make sure that they get a fully informed Commission. Yes. I'm sorry.

The committee, the ACMUI--if the ACMUI, as a committee, believes that the NRC Commission has gotten factually incorrect information, it's my responsibility to make sure they get factually correct information for their decision.

Now I don't know the issue well enough to make that judgment call and I wouldn't try to sway you in either--in any case, but I think the committee needs to decide the significance of the issues.

And a third piece of this is, by the way, if the rule language itself is fine, but it's just the supplementary information or potential future guidance could be issued to correct possible misunderstandings of how the rule's supposed to be used, then we could do that as well.

You know, most every rulemaking has guidance issues associated with the rule, and if clarification points about what types of permanent implant this rule applies to can be done through guidance, that's a third option. That's farther in the future.

Dr. NAG: Can I ask for a clarification.

If the Commission approves this, and, you know, we are in the comment period and it will take some time to get all the commentary back from

everyone, it will take maybe, I don't know, six months to one year before it changes, during this period, this six to one year period, what will happen if--would the rule be enforced or not?

MR. LEWIS: No. The rule would not be effective until there's a final rule. So from the date the Commission says to publish a proposed rule for comment, we would issue a public comment period, which is normally about 75 days, some rules, it can be 90 if it has NAFTA implications, for example, they're ninety. This one probably wouldn't.

So 75 day comment period. At the end of that comment period, the rulemaking working group reconvenes and does comment disposition, where they respond to every single comment or groups of like comments, and republishes that together with the final rule. And no rule would come in effect, you know, at least for a year, and a year is sometimes optimistic if there are a lot of comments.

DR. VETTER: This is Dick Vetter. So Dr. Nag, do you believe that the information provided to the Commission is factually correct?

DR. NAG: I think it's correct but there has been misinterpretation by--there has been some misinterpretation on what--on some of the wordings

that we actually meant, or they were not fully taken into consideration.

So I think just a few minor changes would solve it, and my preference would be that we solve it beforehand, rather than going to the Commissioners, then coming back, then recollecting, sending it back.

If it is possible at this stage to collect what we actually meant and send it to--you know, there would be no major objections from any parties. Is that possible at this stage?

DR. VETTER: This is Dick Vetter. Mr. Lewis, is it possible for you to take a summary of Dr. Nag's concerns, or get those to the Commission?

MR. LEWIS: Well, that boils down to the--here's the--the Commission was given a document to vote on, in its public document. So their voting record is based upon that public document when they issue their votes.

We can supplement the information that they have, but it would have to be through an entirely new public document.

So basically, we'd have to cancel the vote they have before them, which will be a "big deal." But as I said, it's up to the committee to decide if this issue rises to that threshold. If there are

clarifications, it's much easier to handle in the proposed rule stage, or alternatively, if the Commission votes, directs us to change the paper, and those votes--I'm sorry, not their votes, but the Commission SRM itself, which is the compilation of all the votes, directs us to change to paper, if it directs us to change it on issues that are related to your issues, then we could change the words in the **Federal Register** notice, in the proposed rulemaking.

But I don't think in this case, they'll even know your issues, so I'd be very surprised if they commented on this.

DR. NAG: That is why I was wondering, is there a way for us, meaning the ACMUI, to have this concern to the Commissioners when they are voting on the issue? You know, they will know that this concern's out there, and one possibility is that the Commissioners would say yes, we like this but these are some of the concerns, and would the NRC officials address the concern in its final revision, final rulemaking? That would probably be the easiest way to solve this problem.

MR. LEWIS: I think that the only way for us to do that is to retract the paper we've given them, which is possible, but of course that would

delay things quite a bit for this rule.

DR. NAG: But the thing is, it will delay it anyway, because even when it comes back, you know, the reply or the commentary from the people who are doing the permanent implant, will be so strong, that you will have to be redoing what we are saying at this moment anyway, because this is something that all--I mean, the people who are doing the permanent implant all the time would be telling that to you anyway.

Most of the time--

[Simultaneous conversation]

MR. LEWIS: Dr. Nag.

DR. NAG: Yes.

MR. LEWIS: It is a proposed rule, so we published a proposed rule for the express purpose of getting comments, so that we can address them and they can write in the final rule.

DR. NAG: Okay.

DR. VETTER: So Dr. Nag, do you think that would work? You would be commenting on proposed rule changes and the ASTRO community would have the opportunity to comment as well on those, on the proposed rules, and then of course lobbying for changes in the rule at that point in time.

DR. NAG: Right. But basically, the ASTRO

comment is what I have enumerated to you at this meeting anyway. So the NRC already has the ASTRO comments, even though not in writing. Through me, ASTRO can have a similar comment directly through the NRC.

DR. VETTER: Okay. Are there any other comments from any members of the ACMUI?

DR. WELSH: Yes. This is Jim Welsh.

DR. VETTER: Yes?

DR. WELSH: I would say that I agree with, if possible, amending this to correct any misinterpretations that have been made before it moves forth. But I understand that it's actually a much "bigger deal" than we initially thought it was. Therefore, the proposal of reviewing the material in the **Federal Register** and commenting on it may be the most practical solution.

What is the timeframe that we're talking about in this particular situation?

MR. LEWIS: This is Rob Lewis. When the Commission SRM would come out, it would usually take us about two months to--two weeks? Well, if they don't have substantial changes, it can take as little as two weeks before we can publish a proposed rule. If they direct us to change the package, it could go

longer. A month or two.

DR. WELSH: Will there be an extensive period of time for which comments could be generated and gathered and--

MR. LEWIS: 75 days.

DR. NAG: Rob, I have a question. Do the Commissioners review the summary of the ACMUI telephone conference call? I mean, for example, when we have a summary of this telephone conference call, do they look at that? Because then they would have an idea, what we are talking about, even before they vote.

MR. LEWIS: I would be surprised if the Commissioners routinely read the meeting minutes or anything. If there's an issue that we want to call to their attention, we can do a daily note or something, which we often do for public meetings. It's called a daily note but basically it's a highlight of all the things going on in your office.

DR. NAG: My preference would be that if there was a way to do a daily note or whatever method you have--you know, I can make a motion which will summarize whatever we discuss this morning, and in one paragraph, and that would be conveyed to them in a daily note, since they haven't voted on this, because

that would probably solve the thing best, rather than having it already sent out, then public commentary back, and so forth. If that's possible, we can say, you know, the ACMUI recommends that, you know, this portion be revisited.

MR. LEWIS: A daily note won't work for that purpose. A daily note is just information. We can't give them information, we're asking them to consider in their vote, so--a daily note could, for example, say one of the topics of discussion was permanent implant brachytherapy rule, and pass forward when the Commission vote on the paper is.

DR. NAG: Right. And, you know, if they see that there is a discussion item in there, they will look at this, and, you know, when they're voting, I'm sure they will consider whatever the major discussion was, when they're voting. We are not telling them to, you know, to look at this before they vote, but we are telling them that this was discussed in the ACMUI.

MR. LEWIS: Well, the factual aspect that it was discussed, we'll send up. I mean that's--

DR. NAG: Yes; right.

MR. LEWIS: --we don't need your help but we can just--

DR. THOMADSEN: That doesn't sound like that would be very useful.

DR. VETTER: Please identify yourself.

DR. THOMADSEN: I'm sorry. This is Thomadsen.

MR. LEWIS: It would be useful from the point of just information-sharing and maybe it might prompt them to ask more. But I would agree with you, it's not going to really bear upon their decision on the paper, in normal circumstances.

DR. VETTER: Okay. This is Dick Vetter. So the dilemma is whether the ACMUI would like the NRC to withdraw this entire package or whether we think we could provide the appropriate recommendations by reacting to the proposed rule changes.

DR. THOMADSEN: This is Thomadsen again. Can I ask, just for a little more clarification on the part of the NRC staff, what would be the major problem if this were withdrawn? I didn't quite understand that.

MR. LEWIS: It would be put back into the rulemaking queue, and prioritized with other ongoing rulemakings, and it would have to go all the way back through concurrence chain, and it would be very unusual for a paper to be pulled back. In fact, I

can't think of it happening on a rulemaking package ever.

And so it will cause a lot of questions and process examinations.

DR. THOMADSEN: Actually, that sounds like that's exactly what's needed.

DR. NAG: Now is there any way--because this is only one portion of it. The rest of the memo or the rest of the rulemaking were exactly what the ACMUI wanted. It's just one portion where, you know, there seems to be some problem in interpretations, and if the NRC were to correct that on the phone and send it back, I thought--you can fax the message, rather than sending it out to receive a bunch of written comments on it.

MR. LEWIS: That was my original point, is you have--the committee has before it, as Dr. Vetter explained, is the entire package, is "the baby and the bathwater" situation. Is this issue big enough to question the entire package and its timeliness?

DR. NAG: I think the timeliness is not the problem. Anyway, this will not be implemented for the next one or two years. I think it will be more expeditious if the NRC withdrew it, make the minor corrections needed, and then send it back.

MR. LIETO: Question.

MR. LEWIS: Yes. Question by someone?

MR. LIETO: Yes. This is Ralph Lieto. Dr. Nag and Dr. Thomadsen, as to the issue of specifically the wording that states brachytherapy sources implanted beyond 3 cm from the outside boundary of the treatment site, except for brachytherapy sources at other sites noted in the pre-implantation, implantation, written directive, end quote.

DR. NAG: Yes. That's number one. That's the major one. The others are minor. As I have explained before, the other two things are minor and can be, you know, more easily solved. But the major one, like problems of medical implants that I have been talking about. The other one--you know, where is the treatment area versus, you know--that can, you know, maybe just be by adding that the treatment area is defined as the organ of concern plus a variable margin as defined by the authorized user, or something like that. Cause that portion is minor. But the major one is that 3 cm beyond. Not even one source can be outsourced at 3 cm. That's the major problem.

MR. LIETO: A follow-up question. This is Lieto again. To NRC staff. Is the proposed rules

here, do they take into account the comments of ACMUI? I believe there was a request for comments back in, I'm going to say maybe February or early March, on these proposed, on this proposed drafting of rules.

Does this incorporate those comments?

MR. LOHR: This is Ed Lohr from the rulemaking group. To answer that, sir, we took all the comments that came in during that preliminary language period, if you will, and we broke them into two groups. Those that were in question of the technical basis, we delayed until the public comment period. Those that had suggested language changes, many were incorporated into the rule language before this went forward to the Commission for their vote.

MR. LIETO: A follow-up question. Were we going to be notified of those comments that were not incorporated? Because you felt that they were going to be--that they should be addressed during the technical basis. There are comments that, you know, I know that I supplied, and maybe some others have, that didn't get incorporated, and if there was a reason for this, was there going to be any feedback, which I think gets back again to may be Dr. Nag's original concern, that when these changes were made, these things weren't, you know, fed back to us in any

manner, to be sure that this was the intent.

MR. LOHR: The **Federal Register** notice that has not been issued, because the Commission has not told us to issue it yet, answers many of those questions.

MR. LIETO: Okay.

MR. LOHR: You know, if you'd like to refer back to that, the SECY paper which is public, but again, the Commission has not voted on that, so we at the NRC cannot really respond to that.

DR. NAG: No. I think the question was even earlier. After the February 7th notification, there were many comments sent back to the NRC, including a letter from ASTRO that had some of these concerns, that they were concerns, that they were concerns, and I think Mr. Lieto's question is that, you know, were all these concerns incorporated, or would they not be incorporated because of technical reasons.

MR. LIETO: All the comments we get are considered in drafting the package. There's no step in the rulemaking working group, where they do a point by point response to all of the comments. That occurs between the proposed rule and the final rule.

DR. VETTER: This is Dick Vetter. We are

quickly running out of time, using up our time. Before I ask for some more specific action on this item, I'd like to open up to members of the public, if someone has some comments to make, and if you do, please identify yourself and keep your comments to two or three minutes.

Any members of the public wish to comment on this issue?

MS. MARTIN: Dr. Vetter, this is Melissa Martin with AAPM. I would just like to reiterate what Dr. Nag has been saying. I worked with Dr. Nag on another committee for ASTRO, but I've had a lot of experience with these brachytherapy seeds, well over hundreds of implants at this point, and I can only reiterate these seeds to migrate. It may not be the intention of having a seed 3 centimeters out, but it certainly happens, not uncommon at all, and I think it's going to be a major problem.

DR. VETTER: Thank you. Any other comments?

DR. NAG: Unfortunately, we do not have the clinical developers who were on the ASTRO conference call. They are not on here. But I mean, that you have heard similar things from the ASTRO members who are doing the implants but they are not on

the conference call.

MR. MARTIN: This is Richard Martin from ASTRO. I would like to say that we did have a conference call with a number of people, who routinely do brachytherapy procedures, and there is an enormous amount of concern about migration, about what is considered the appropriate treatment area, and we did respond to the earlier proposed or pre-proposed rules, voicing some of these same concerns.

DR. VETTER: Thank you. Any other comments from members of the public?

DR. ZELAC: Dr. Vetter.

DR. VETTER: Yes?

DR. ZELAC: This is Dr. Zelac, NRC.

DR. VETTER: Yes?

DR. ZELAC: It's probably worth noting in the discussion at this point that the seed migration currently, and in the future, is not considered as a basis for a Medical Event. It's understood to occur, when it does occur, it is noted, but it is not a reason for any clinician, or anyone else, to report that occurrence as a Medical Event.

DR. WELSH: This is Dr. Welsh. May I comment?

DR. ZELAC: Certainly.

DR. VETTER: Yes.

DR. WELSH: Item number seven in our background on the rulemaking issue notation vote that was e-mailed, states specifically that seeds that were correctly implanted, but subsequently migrated, are excluded as grounds for any ME.

DR. NAG: Hi. This is Dr.--

DR. WELSH: Getting back to that point about the "bathwater," it would seem that there's a very simple solution that might be able to solve all this very quickly. If that sentence were to be expanded a little bit further, I think all this would go away.

DR. NAG: Hi. This is Dr. Nag. When I had given my introductory part, I had mentioned that, you know, seeds that I implanted but are migrating are not grounds for ME. However, there are different kinds of migration. One is a distant migration going into the lung or very distant organs like the heart, which has happened. That is very easy to know that this is migration and therefore no one is going to question about that.

But the second part, which is very difficult to distinguish, is when they migrate into a pelvic vessel and they migrate only 3 or 4 centimeters

away. Then you don't know whether it was the seeds that were implanted there or migrated there, unless you have been taking x-ray every 10, 15 minutes, which no one does.

So Ron, we do recognize that distant migration is not a problem and not an ME, but our worry is that migration at the nearby site, or just something of a seed along the middle tract would be considered a, by the definition given here, would be considered a Medical Event.

DR. MALMUD: This is Malmud. First of all, I apologize for having joined the call late, and I appreciate Dr. Vetter's chairmanship.

The comment that I would make with respect to the seeds is that if it's not a Medical Event, what is--it's a question. If it's not a Medical Event, as Dr. Zelac points out, what is the current concern among the radiotherapists?

DR. NAG: Oh, I'm sorry, you didn't--probably were not at the beginning of the call.

DR. MALMUD: I was not.

DR. NAG: The first ten minutes, I had given--basically, one, it's that when you do put the seeds and you're pulling the needle back, you can suck one or two seeds, when you're pulling your needle

back, and if you're sucking it more than 2 or 3 centimeter away, that would be considered a Medical Event when it's not.

Secondly, when you're putting the seeds in, some of the seeds can go through a smaller blood vessel and instead of migrating to the lung or the heart, it could migrate to a very prosthetic area, in which case it's more than 3 cm away but it doesn't seem far away to be a migration and therefore it will be considered that you put the seeds there.

So those are at least two reasons. A third one is you can put the seeds into the urethra or into the bladder, and that, with only one centimeter away, and that will flow through the site and it may stop and be, you know, slightly more than 3 cm away.

So the major concern is that those who are clinically doing implants, and have done thousands of these implants, have seen that there are a small percentage of sources that do end up more than 3 cm away, that have not caused any untoward events to the patient, and that is not a cause for any concern, but the current definition, it would be a Medical Event. So that's the major source of concern for us.

The other is that what is the definition of the treatment site versus the treatment organ and,

you know, how much of the periphery just beyond the organ is still considered to be within the treatment area, and that seems to have ambiguity enough, that that could be a cause for concern.

DR. MALMUD: Thank you for clarifying that. I would then ask, if I may, Dr. Zelac, which of the situations described by Dr. Nag would be considered a Medical Event?

DR. ZELAC: The wording of the proposed rule, which was based on the recommendation of the Advisory Committee, had a very clear delineation between seeds placed within 3 cm from target area, beyond 3 cm from the target area. If a seed were placed--and again this gets to the concern of Dr. Nag, as to knowing whether a seed was placed there or simply migrated there.

But if a seed showed up at a distance of greater than 3 cm from the target area, that is the way we perceive and have interpreted the recommendations of the Advisory Committee, would be considered as a Medical Event.

DR. MALMUD: Thank you, Dr. Zelac.

Dr. Vetter.

DR. VETTER: Yes?

DR. MALMUD: Do you recall? Was that the

intent of the ACMUI?

DR. VETTER: I think it was at the time, but I'm not sure that we understood the implications that Dr. Nag has currently outlined relative to, you know, seeds--that's the correct word. As he mentioned, when you're withdrawing the implant device--

DR. MALMUD: Yes.

DR. VETTER: --the seeds can travel down the path, and there's not much you can do about that.

DR. NAG: Hi. This is Dr. Nag. I was on the Medical Events Subcommittee and most of the discussion in fact came from me. You know, therefore I'm aware of what I said and what I meant, and my major concern is that, you know, we could have meant one thing, and it had--some of the wording had not been correctly interpreted and that's giving rise to the problem, which is why I personally sort of have a lot of obligation, that many of these things were taken from my wording, and I am--you know, this led to rules that will create problems for clinical radiation oncologists. You know, I personally, I have a lot of personal ties to this rulemaking.

DR. MALMUD: I understand that, and my understanding is the same as--my memory of it is the

same as Dr. Vetter, that we did discuss this, and it appears that we have made a joint error in not considering that element of--when we made our decision. Therefore, that being the case, we need to find some way of correcting this, so that we do not interfere with the practice of radiation oncology with regard to brachytherapy.

DR. WELSH: This is Dr. Welsh. May I add a comment here?

DR. MALMUD: Yes.

DR. WELSH: I, and most practicing medical radiation oncologists, would probably not disagree, that if you implant the seed, as an example, prostate brachytherapy--if you implant the seed more than 3 cm beyond where you want to put that, I think most people would say that is a Medical Event.

But I think the question here is regarding a seed that is placed within the correct volume, prostate, for example, and subsequently is dislodged, and then winds up more than 3 cm beyond the planned boundary.

Now we have wording here saying that if a seed migrates, it is excluded as grounds for any Medical Event. If we could just add the word "dislodged," all this would go away.

DR. MALMUD: This is Malmud again. Dr. Nag, would that satisfy your concern?

DR. NAG: I will have to think about that, because the major problem is how do you--how would someone know that was it a seed placed within the target volume and it dislodged, or was it placed 3 cm away? I mean, if it is very far away, you know that no way a needle would have been placed into the lung, and therefore that was a distant migration.

How are you going to know a seed that was 3 cm away? Was it placed there or was it placed into the target tissue, and when you are pulling your needle back it ended up there? That would be difficult to, or impossible to know, and therefore my suggestion was that we know that a few seeds to end up more than 3 cm away, and we make allowance for that, because a few seeds outside, it doesn't matter whether you call it a Medical Event or not. It's not a problem. And we know that in the lung that happens all the time, and we know it's not a problem. And so we make allowance for that.

The second thing being that, you know, the NRC is not a medical team and it should not be directing how, in the planning process, how many percent of the seeds should we be placing in the

periphery, how many percent just outside, and, you know. So that's where it is an issue.

DR. VETTER: This is Dick Vetter. Dr. Nag, I would like to suggest that at the time that a seed that may have been dislodged is discovered, it would be up to the treatment team to decide whether that had been dislodged, or whether it had been implanted inappropriately.

DR. NAG: That is easy to say in a meeting, but in practice, having been one of the consultants who looked and investigates into this report, it's very hard, because one person would say, oh, well, you put the seeds 3 cm away, the other would say no, we put it in the right place and it did go out. But the only thing we can say clinically, only a small percentage that comes outside.

So what we are trying to distinguish is whether it was just a few odd seeds that are more than 3 cm away as opposed to a whole bunch of seeds that were placed either in the bladder, or, you know, way down in the perineum, and that was the reason for making up some of the rule change, to detect a gross error, not a few seeds coming loose. And I think this is where the NRC fails to distinguish what we were trying to do.

We were trying to prevent gross error. I was all for having the language strengthened up, so that we detect errors, where 20, 30, 40 seeds have been placed in the bladder, but not where one seed has gone into the bladder and it's floating somewhere in the bladder, and ended up sort of staying 3 and a half cm away.

DR. MALMUD: This is Malmud again. Dr. Nag, what is your proposed rewording?

DR. NAG: My proposed rewording would be that a small percentage--and we can discuss whether 5 or 10 or 15 percent--that we all a small percentage before we call it a Medical Event. Right now, even if one seed goes more than 3 cm away, you are defining it as a Medical Event. I would say that if there are more than--you can put in the number 5, 10, or 15, whatever number you want, is beyond 3 cm from the implant site, it would be a Medical Event. That would, you know, solve the problem. That number--you know, my suggestion would be 10 percent or 20 percent, but, you know, that's something we can work on.

DR. VETTER: This is Dick Vetter. Dr. Malmud, I'm not sure when you actually tuned in to the discussion, but we really have a dilemma here about what action we might take today.

The reason we have the dilemma is because the proposed wording is before the Commission.

DR. MALMUD: Yes.

DR. VETTER: So we really only have basically two options. One is to recommend to the NRC that they withdraw the package, which would be a very unusual step. The other would be to wait for the proposed rule change and then comment on the rule change.

DR. MALMUD: What's the feeling of the majority of the committee? It seems to me that this is something which we reviewed, we came to a recommendation for, and now we wish to recognize as something that we missed.

DR. NAG: I would like to correct you. It's not something we missed. It is a recommendation we made in 2002 or 2003--or actually 2004. We made the recommendation. It went to the NRC but it did not come back through the ACMUI, and that was part of my major objection or concern, that the NRC--I mean the ACMUI makes recommendations, and then the rulemaking is done, without coming back to the ACMUI to check whether, Was this, indeed, what you meant? So I do not agree with you, that this was something the ACMUI missed. We did not miss it. It never came back to

us.

DR. MALMUD: Well, Dr. Nag, we did discuss it and I remember the discussion. But I also remember, but I don't have the details, that there was a discussion about the distance.

DR. NAG: Yes; there was.

DR. MALMUD: Therefore, we did allow it to move forward to the NRC. You are correct that the NRC didn't send it back to us for a re-review but our initial review did go before them.

DR. NAG: Yes.

DR. MALMUD: It doesn't really matter, terribly much, who is responsible for the current dilemma, but we do have a dilemma, and we need to deal with it currently. So we really have two choices as Dr. Vetter has reviewed for us.

By the way, I didn't answer your question, Dick. I came in around 2:00 o'clock.

DR. VETTER: Okay.

DR. MALMUD: The answer is one of the two options, to totally withdraw it, or move it forward and then comment on it at the next step.

MR. LEWIS: Dr. Malmud and Dr. Vetter, this is Rob Lewis. For what it's worth from the NRC staff perspective, and having done many rulemakings

myself, this type of issue can be easily addressed as comment disposition on the proposed rule. If we were to get a comment on this area, it can be changed before the final rule.

That doesn't mean that the committee has to go that way, but in terms--and the most efficient and effective way to get throughput in, that would be from the NRC staff perspective the preferred way.

DR. NAG: I have a question.

DR. MALMUD: Oh. Go ahead.

DR. NAG: Mr. Lewis, there was the commentary period in February, I believe it was the February 7th memo, and ASTRO did give a response, basically saying similar things I'm saying today. But that was not incorporated, and it went on to the Commissioners anyway. So I think that's a major concern, that the radiation oncologists have, that they did make the comment and that was never addressed, and just went up to the next level.

MR. LEWIS: There's an issue of, when we do a--it's called an enhanced participatory rule--that's where we would involve the public and specialty groups, prior to the proposed rule being developed, and in our process, those comments are considered. An individual comment response document is not generated.

In the proposed rule stage, we are required, by law, to consider and disposition every comment, and the fact that--I grant that, you know, as you perceive the ACMUI and ASTRO comment, they weren't incorporated into the proposed rule package, and that is either an issue that the staff disagreed with the comment, which I don't believe is the case, or that the staff didn't fully understand the comment.

That's unfortunate, but that is where we are, and the question then becomes how to correct that, where we are, and in that regard this whole discussion reminds me of a big topic of discussion from the last ACMUI meeting, of how the NRC staff gets back to the committee on any comments we seek from you.

I think that is an area that's broader than this rulemaking, but that we do need to explore, to make sure that we're all clear on roles and responsibilities, and what we communicate with each other, before and after seeking comment.

DR. MALMUD: This is Malmud. I think we agree with your comment, and that's the point that Dr. Nag is pursuing. Once again, though, we come back to the current issue, and that is the specific issue. So there are two options. One is to withdraw the entire

affair, the other is to let it move forward and to have the comments ready.

However, I would point out that if we have our comments ready, and we're looking for a percentage of seeds that are acceptable, that that percentage number should be a number and not a descriptive such as "small," because what's small to one person may not be to another, and I think that the NRC would probably request of us something firmer than an adjective.

Am I correct in making that assumption of the NRC?

DR. NAG: I agree with you.

DR. MALMUD: All right. So that would need a little more discussion, particularly among those who are responsible for this type of therapy, which are the radiation oncologists, and the radiation oncology physicists.

DR. NAG: I agree with you, and again my concern is that there is a 75 day public commentary period. We may not be able to come up with a number because trying to get a meeting of a lot of people takes time, and then to get an agreement, whether it's 5, 10, 15 or 20 percent, will take a lot more time, and, you know, my reasoning therefore was to say let's take this back, send to the Commissioners a correct

statement of what we really meant.

DR. MALMUD: All right. That's your recommendation.

DR. NAG: Right.

DR. MALMUD: Dr. Welsh.

DR. WELSH: Of the two options, I would prefer that. It sounds like there was a misunderstanding or misinterpretation of Dr. Nag's comments, and he never had a chance to edit the written version, and now this written version that is coming up is the cause of all this consternation today.

DR. MALMUD: Is there precedent for this kind of an action? I'm asking NRC staff that.

MR. LEWIS: Commission papers have been withdrawn, but I don't know of a rulemaking package that's so close to being issued, that has been withdrawn like this. I'm Robert Lewis.

DR. MALMUD: So it may or may not be possible.

MR. LEWIS: Well, the recommendation of the committee, we'll do our best to get that up to the Commission. If it went that way, we would do our best to get it up to the Commission as soon as possible, so that they can consider it. You know, if they were to

vote--we had expected them to vote by now, so if they were to vote today, or this week, you know, ships might pass.

DR. MALMUD: Yes.

MR. LEWIS: But that being said too, the NRC management up the chain--and even the Commission will be looking for a very high bar to withdraw something that's so close to issuance, and a high bar would have to be material information being factually incorrect, and that's kind of--we'll have to rely on the committee's recommendation in that regard.

If it's an issue of clarifying words, or not actual rule language that's a concern, but the supplementary information--you know, my management chain probably wouldn't support withdrawing the package. It'd just be--you know, we would have the option, as well, of considering the comments in the proposed rule for disposition.

DR. MALMUD: Okay. I understand. All right. Someone wanted to make a comment, I believe.

MR. LIETO: This is Ralph Lieto. I'd like to make a comment. I'd like to make a motion, and I think that our best alternative is to address this very, very strongly at the proposed rulemaking point.

If we're going to have to provide some

type of factual basis for having this withdrawn to NRC staff, obviously, probably in the next day or so, I just think that we may, as Mr. Lewis said, we may "miss the boat." And I think if we just go on record as stating our concerns, that our recommendations are not being addressed properly, as Mr. Lewis has already described, which I think is a big problem, I think we should just prepare ourselves to address the proposed rule when they come out since we've already got essentially an advance notice on what they're going to state.

DR. MALMUD: So if you're making a motion, Mr. Lieto, your motion is that we allow it to move forward and prepare the comments in the time allowed with regard to a proposed amendment to the rule, or a proposed further interpretation of it?

MR. LIETO: So move.

DR. MALMUD: Mr. Lieto has made a motion.

Is there a second to Mr. Lieto's motion?

DR. VETTER: This is Dick Vetter. I second the motion.

DR. MALMUD: Dr. Vetter has seconded the motion. Is there any further discussion of the motion, which will include, from what I interpreted Mr. Lieto to say, a recommendation regarding how

information should be--how we would propose that the information that we move forward come back to us for re-review after it's been reviewed by the NRC staff. Is that correct, Mr. Lieto?

MR. LIETO: Yes.

DR. MALMUD: All right. So we have a move by Lieto, seconded by Vetter.

Any further discussion?

DR. THOMADSEN: Yes. This is Thomadsen and I just would like to get Dr. Nag's "take" on the motion.

DR. MALMUD: Dr. Nag.

DR. NAG: Yes. Well, I do not agree on the motion but I will vote "nay" when it comes to voting.

DR. MALMUD: Thank you. All right. So--

DR. THOMADSEN: Can I--this is Thomadsen again.

DR. MALMUD: Yes?

DR. THOMADSEN: Dr. Nag, if you're voting against the motion, what would you like to see different in the motion?

DR. NAG: I would like to make the motion that--well, that will be entirely different motion. But I think that because there has been--the entire

rulemaking was based on the recommendations of the ACMUI. We give you that. However, there were misinterpretation and therefore it did not go--it has been shown to the Commissioners that this was the recommendation but with a wrong interpretation on some areas where there have not been interpreted properly, and therefore I'm against it because it shows to the Commissioners that this is what the intent of the ACMUI was, when it was not the intent of the ACMUI.

And even a few wordings change makes such a huge difference in the rulemaking, that we are setting up ourselves for major problems later, and I wish to prevent the problem from occurring, rather than letting it go forward, having the problem occur, and then try to rectify later.

DR. THOMADSEN: This is Thomadsen again. Mr. Lieto, what do you say to that? How would you answer Dr. Nag?

MR. LIETO: Well, my reasons for putting this forth are twofold. One, I really don't want to see this thing get buried at the bottom of the list again, and probably not reach fruition in our lifetimes.

The second reason is by putting it into the proposed rulemaking, it requires that the NRC

address our comments and provide factual justification for leaving things either as is, or not changing them, and I think the staff will--well, I can't speak for NRC staff cause I've always been wrong on that point.

But I think that if the ACMUI comes out in a unified voice, supported by the professional communities saying the same things, I really think that the NRC would see the wisdom of making the changes and this would be accomplished without a delay, that would occur if we went forth in pulling it as per Dr. Nag's intent.

DR. THOMADSEN: This is Thomadsen again. Can I ask anybody on the NRC staff if they feel that Mr. Lieto's "take" on the NRC staff's response would be correct?

MR. LEWIS: Yes. I think that--this is Rob Lewis. The NRC staff's view is that the most efficient way to get any fixes that may be needed into a rule, would be through the proposed rule comment process, and so withdrawing the paper would delay this rule. The objective could be achieved without any delay in the rulemaking, is where I'm going, rather than going back to the Commission with a new paper.

And the other piece, there is a trickle-down effect, even if this rule were to be put high on

the list and go up, then, you know, other rules on the same subject, resources would have to be diverted from those. So future Part 35 rule might be delayed as well. So there is a trickle-down effect of withdrawing the package from the Commission that'll broadly affect our rulemaking, because everything is lined up, people's availability, some incredible schedule they maintain, to track who's working on what at any given time, and it all gets "thrown out of whack."

All that being said, you know, the committee's--that's just the NRC staff's view, and I'll do my best to make sure whatever the committee's view is is heard upstairs.

DR. VETTER: This is Dick Vetter. May I ask a question, Mr. Lewis?

MR. LEWIS: Of course.

DR. VETTER: We may have asked this before, I'm not sure, in all our discussion here, but is it possible for the committee to prepare a letter that would go to the Commission to provide clarification on this issue before their vote?

MR. LEWIS: I believe--I know some things that I can't discuss, but I believe that would be very difficult.

DR. VETTER: Okay.

MR. LEWIS: If you wanted to write a letter, I would do it, you know, this afternoon.

DR. NAG: I can prepare a letter within two to three hours, that I can send to the ACMUI, and, you know, and still--I mean, I can have it prepared in a few hours. Or by tomorrow, let's say.

MR. LEWIS: Well, as I was talking about earlier in the call, I think it might have been before Dr. Malmud--the Commission may be, in that situation, in a legal bind, because they have to consider the information on the public record before them, which is the paper we deliver, and make their vote on that paper. I don't know the legalities of the Commission operations, or a supplemental comment by anybody, ACMUI or anybody else, on a paper before them is very out of process, and even if they could consider it, they'd want to run it through a bunch of attorneys to find out if they could.

DR. MALMUD: Thank you. This is Malmud addressing a question to Dr. Nag. Dr. Nag, would it be possible for us to have a subcommittee meeting in the near future, as soon as possible, with a recommendation from you regarding the new wording, move ahead--let this process move forward and then

have a comment immediately prepared for the document as it goes through.

DR. NAG: So you mean prepare a letter or prepare our comments, assuming that the rulemaking process comes out--

DR. MALMUD: Yes.

DR. NAG: --so that within that 75 days we would have a response?

DR. MALMUD: Yes.

DR. NAG: Yes; that's possible.

DR. MALMUD: Then the next question I have is for NRC staff. Is it possible for us to have a subcommittee meeting, or does it have to be a public meeting?

MS. TULL: No, it does not have to be--this is Ashley. It does not have to be a public meeting, Dr. Malmud.

DR. MALMUD: So we could have a subcommittee conference call meeting any time we wish?

MS. TULL: Yes. I can arrange that for you.

DR. MALMUD: And the interested parties in that would, of necessity, be any members of the radiation therapy world who are on our committee, and a committee chairman for that subcommittee. Would

that be acceptable to the parties who are interested? Dr. Nag, Dr. Welsh, Dr. Vetter, Mr. Lieto?

DR. WELSH: I am fully supportive. Jim Welsh.

DR. NAG: Dr. Thomadsen also.

MR. LIETO: And I would too.

DR. MALMUD: Dr. Thomadsen, I'm sorry. I know I left a name out. Sorry. Yes. Okay. So may I make--so we have a motion on the floor. We have had discussion, and I've made a recommendation that I don't think requires anything other than your having just agreed to have the subcommittee meeting, and we'll do that as promptly as the chairman of the subcommittee wishes to call us in conference call.

Within the next two weeks?

DR. NAG: You need to have the chairman of the subcommittee.

DR. MALMUD: And I think if it's agreeable, Dr. Nag, since you have such an intense interest in this and concern about it, would you be willing to chair the subcommittee.

DR. NAG: I will.

DR. MALMUD: Is that acceptable to the committee members?

[Chorus of yeses]

DR. MALMUD: Thank you. All right. So now can we move on this motion. All in favor?

[Chorus of ayes]

DR. MALMUD: Any nays?

DR. NAG: Nay.

DR. MALMUD: Dr. Nag votes no. Any abstentions?

[No response]

DR. MALMUD: Thank you. So the motion moves forward and we will have a subcommittee meeting via telephone conference call which Dr. Nag will chair, and try to come up with a document that establishes a standard which is both practical and in the interest of public safety and welfare.

DR. ZELAC: Dr. Malmud.

DR. MALMUD: Yes, Dr. Zelac?

DR. ZELAC: If I can take 30 seconds, I'd like to just put a little bit of historic perspective on this.

DR. MALMUD: Please do.

DR. ZELAC: The proposed rule, it went out for input on its language, which was rather unusual to be done, but in this case we felt it was good and useful to do so, was reflective of the comments, the specific recommendations that we received from the

entire Advisory Committee, in terms of half a dozen very specifically worded recommendations for inclusion in the revised rule.

There were comments that were received, based on what had been sought in February when the draft proposed rule went out, dealing with the language of the words themselves, and those were considered and incorporated as appropriate.

There were other comments received, which would have included those like Dr. Nag, on the substance of the proposed changes, that were, by conscious decision, deferred, not put away, simply put to the side to be considered at the time that the proposed rule was published.

So it may seem to Dr. Nag, at this point in time, that what he had to say was not being considered or acted upon, but that was a conscious decision, to not act upon it at that point in time, not to discount it at all but to give it thorough consideration when all comments from other individuals dealing with the substance of the proposed changes were received after publication of the proposed rule.

DR. MALMUD: Dr. Zelac, thank you for the clarification and I think that we all recognize what has occurred, and at this point we all will share in

the responsibility for trying to come up with the appropriate language that will satisfy both the needs of the public, patients, as well as the practical aspects of radiotherapists.

May we move on?

DR. VETTER: Yes.

DR. MALMUD: Thank you. Dr. Vetter, I thank you once again for a yeoman's job in my absence.

The next item was the--did you do the part--well, actually, this covers it, doesn't it? Was there something else--?

DR. VETTER: Number two is technical basis to support rulemaking in response to the Ritenour petition.

DR. MALMUD: Support rulemaking in response to the Ritenour petition. Okay.

DR. NAG: One second. As part of the previous one, we made the voting, I would like to add an additional motion. That if a recommendation is made by the ACMUI to the NRC, that the NRC gets back to the ACMUI with a draft before they proceed to make a final rulemaking. But that would present this sort of thing from happening in the future. Is that something I can put forward at this point?

DR. MALMUD: You can certainly make such a

motion as a form of a request to the NRC.

Is there a second to that motion as a request to the NRC?

DR. WELSH: I second it.

DR. MALMUD: I'm sorry. Who spoke?

DR. WELSH: Jim Welsh here.

DR. MALMUD: Dr. Welsh seconds the motion. Is there any discussion of the motion?

[No response]

DR. MALMUD: All in favor of the motion?

[Chorus of ayes]

DR. MALMUD: Any opposed to the motion?

[No response]

DR. MALMUD: Any abstentions?

[No response]

DR. MALMUD: The motion moves forward as a request of the NRC with the unanimity of the committee. Thank you, Dr. Nag.

And we are still with the technical basis to support the rulemaking in response to the Ritenour petition?

DR. VETTER: Correct. We had not started that one.

DR. MALMUD: Who wishes to address the subject?

MR. LOHR: The next issue--this is Ed Lohr for rulemaking.

DR. MALMUD: Yes.

MR. LOHR: I want to talk about the actual **Federal Register** notice that announced the outcome, if you will, of the Ritenour petition, and I want to bring to the community's attention the very last paragraph of that **Federal Register** notice, which we've provided to all the ACMUI members. And that is the conclusion of the Ritenour petition and what is required to actually get this into rulemaking space.

Understand, first of all, when we published this in the **Federal Register**, it closed the petition. The petition is now officially closed in the NRC and in the public's eye. In closing this petition, we also went on to say that we would consider it in rulemaking space but we needed additional data to support what we call a technical basis, which the medical group will actually be developing to send to Rulemaking where I work.

I want to make it very clear, that a technical basis is not done, is not submitted, or is not valid, this rulemaking will not occur. And that's what it says in the **Federal Register** notice, and I want to make sure that's very clear and very

understood.

Having said that, I know that the NRC medical staff here wants to get this to rulemaking space. I understand they're going to be doing various activities to solicit, if you will, the medical community for data to support the technical basis.

But I want to make that very clear, and if there were any questions on that, I'd be willing to address those at this point.

DR. MALMUD: This is Malmud. Are there any questions?

DR. VETTER: This is Dick Vetter. Mr. Lohr, could you give us an example of what you mean by "data to support technical basis."

MR. LOHR: That information, sir, will be coming from your medical group, who's leading this discussion, if you will. They're the responsible organization for creating this technical basis, and so they will be addressing that here shortly, I believe, as what the specifics are.

Again, I do not make the determination whether there's a technical basis or enough data. They have to provide that to our rulemaking group, and there's a committee that reviews it. So it's not done in a vacuum, by any means.

DR. ZELAC: Dr. Malmud.

DR. MALMUD: Dr. Zelac.

DR. ZELAC: I think that I can add a few words that may provide the clarification that's required.

DR. MALMUD: Thank you.

DR. ZELAC: The intent of NRC staff, specifically the medical group, at this point is as Mr. Lohr has said, is to solicit from the user community the kind of information that can be used to form the technical basis of which he spoke. The intent, at the moment, is for us, NRC, to send letters to certifying boards, specifically those who were listed in Subpart J, which certainly includes those who are now currently recognized by NRC or the Agreement States.

And those letters will solicit information on the numbers of actors, individuals, who are certified prior to the recognition of a board process. As I said, most of those that were listed in Subpart J have, at this point in time, been recognized, re-recognized, if you will, by NRC or Agreement States. A couple are still pending.

But in all cases, those individuals who are certified as of the date of recognition, and

beyond, meet the criteria to apply for authorized status via the board recognition pathway, certification pathway. But those who were certified prior to the board processes being recognized are those for whom there may be some benefit to further consideration of the current rule.

It's to look at those individuals, certified prior to recognition of a board process, to determine how many of them are active individuals who now, or in the future, might seek to be listed on a medical use license.

DR. MALMUD: Okay. So it's get the database as to how many individuals among those boards might require grandfathering?

DR. ZELAC: That's correct. Those individuals, in that category, prior to board recognition, were certified, who are not listed on licenses, to whom any modification of the current rule might be beneficial.

DR. MALMUD: And what you're telling us is that these letters will go out, and we will expect those boards to answer in a timely fashion?

DR. ZELAC: That is correct. That is the plan at the moment with respect to our actively soliciting, and hopefully receiving, the information

to make a determination as to whether or not the technical basis exists to pursue rulemaking.

DR. MALMUD: And our assumption is that those boards have those databases?

DR. ZELAC: My presumption is that they will have to, these individuals boards will either have, or more likely than not, would be soliciting their members--

MR. LEWIS: Dr. Malmud. No.

DR. ZELAC: --to gather this information.

MR. LEWIS: Dr. Malmud.

DR. MALMUD: Yes?

MR. LEWIS: This is Rob Lewis. I'm sorry to interrupt. I am going to have to go to another meeting in the other building and I'm going to have to leave the call now. We went long on the first topic but I think it was very important.

DR. MALMUD: Yes.

MR. LEWIS: I apologize for having to leave, and if there's anything you need coming out of the call, just let me know.

DR. MALMUD: Thank you.

Dr. Zelac?

DR. ZELAC: I have nothing further to say on the issue but I will answer any questions that

individuals might have.

DR. MALMUD: Are there any questions for Dr. Zelac?

MS. FAIROBENT: Dr. Malmud, it's Lynne Fairobent with AAPM. May I ask a question?

DR. MALMUD: Please do.

MS. FAIROBENT: Ron, could you clarify, because I think I heard two different things as to what you said the letters to the boards were attempting to get. Are you simply attempting to get the number of individuals certified by any of the boards prior to the October 2005 date versus those who are now eligible based on the effective date?

DR. ZELAC: No. The October 2005 date, when Subpart J disappeared, is not a factor at this point in time. What is a factor, and will remain a factor, are the dates of recognition of the individual board certification processes. Any, as I said, and you recognize, any individual certified after those dates are good, if you will, in terms of applying through the certification pathway, whereas those who are certified prior to those dates, who have not made application and had been recognized, and authorized on a license, are the persons to whom this potentially could apply, and of those, it's the subsets who, at

this point, believe that they may, or are seeking to be listed as an authorized individual on a medical use license.

DR. MALMUD: This is Malmud. Does that answer your question, Lynne Fairobent?

MS. FAIROBENT: Dr. Malmud, yes. I believe the board would have no knowledge of whether or not an individual practitioner of any type is currently listed on a license, or in the future may be seeking to be listed on a license.

DR. ZELAC: Well, that's exactly what this--

[Simultaneous conversation]

MS. FAIROBENT: That is not data the boards would have.

DR. ZELAC: That's exactly what I said before. I don't expect that the board would have this information, but it's something, has surfaced to their diplomates, that they would perhaps feel appropriate to pursue in terms of a questionnaire.

MS. FAIROBENT: A question, Ron, then. NRC would know who is on a license. Why does NRC not have that data?

DR. ZELAC: Because you're seeking more than simply that. You're seeking primarily those who

are not listed on a license, and also those who might in the future, or are now currently considering being listed on a medical use license.

Now those on licenses aren't an issue. Those are--they would gain no benefit from this anyway, 'cause potentially they are grandfathered in the current rule. It's those persons that are not listed on the license to whom this applies.

DR. VETTER: Ron, this is Dick Vetter. I guess the point I would make is that all of those members of those boards who'd been certified have the potential to apply for an RSO position.

DR. ZELAC: Absolutely. If that was the information that came back from the boards, then, you know, that would be what we would take into account.

But clearly, some of the people that were certified prior to the board recognition, board process being recognized, are not active at all, have retired, or deceased. So it's simply not looking at the list of everybody that's been certified and saying everybody might, potentially, in the future, want to be listed as an authorized individual on a medical use license.

DR. VETTER: This is Dick Vetter again. I think the boards would have that information.

MR. WHITE: This is Jerry White from the AAPM, Dr. Malmud.

DR. VETTER: Go ahead, Jerry.

MR. WHITE: Ron, I hear two things. The first is that you said that you would inquire of the boards which of their members might find an advantage to this potential rulemaking. And then you went on to describe certain classes of people, who either you, or the NRC, believed would fit that definition, and I want to be certain that your inquiry is to have the boards offer an opinion as to who might find this change beneficial rather than--

DR. ZELAC: Well, data would be better than an opinion, clearly.

MR. WHITE: Well, my question is: Will you decide, or the NRC decide, who will benefit, or will the boards be permitted to decide who will benefit?

DR. ZELAC: More than being permitted, it's the input from the boards that we receive at NRC, that will form--that can be used as the basis. It's not the combinations on our part. It's based on the information that's provided.

Now clearly, we have to be very clear in what we are suggesting as appropriate. But if the board wants to add some additional information, that

they feel would make even a stronger case, or whatever, that's fine. This is something that, you know, is not cast in stone at this point.

I can't say that we have a letter ready to go out the door tomorrow. What we're thinking in this time, and in this direction, so input from this discussion of course will be useful for that process.

DR. MALMUD: Jerry, did that address your--I'm sorry. I can't hear you clearly. Did that address your concern?

MR. WHITE: I think we'll have to wait until the letter comes out.

DR. MALMUD: Okay.

MR. WHITE: But I would hope that the NRC would allow the boards to offer data on--would allow the boards to decide what class of individuals this change would benefit, rather than have the NRC make a determination as to what class of individuals this change would benefit. That's an important distinction, and I would hate for the NRC to unnecessarily limit discussion in that regard.

DR. MALMUD: This is Malmud. I suspect that the NRC would respond well, and the boards should describe these individuals with the board's recommendation, giving the NRC both the answer to its

question and recommendations. Hopefully the NRC will respect the opinions of the boards, will certainly hear the opinions of the boards, if they're expressed.

MR. WHITE: Thank you.

DR. MALMUD: Is it fair for me to say that? I'm not a member of NRC.

DR. ZELAC: No, I think it's--this is Zelac. It's perfectly understandable.

DR. MALMUD: Thank you.

DR. ZELAC: But I think, in particular, since the petition came from AAPM, that there should be an understanding on the part of all of the boards, that generalities, in terms--really won't be enough.

There were sufficient generalities in the petition to raise the question, but the Commission wants there to be a sound technical basis to put resources into the rulemaking. There needs to be a problem to be addressed for a reasonable number of people, beyond those who could be accommodated perhaps by exemption.

DR. MALMUD: So what I infer from your statement is that the more justification that the boards can offer in supplying their data, the more likely it would be to be accepted.

DR. ZELAC: That is correct.

DR. MALMUD: Thank you, Dr. Zelac. May we move on to the next item?

MR. MATTMULLER: This is Mattmuller. I have a question for Ron.

Ron, as a board-certified nuclear pharmacist, are you intending to, even though we're not specifically addressed by the AAPM petition, are you going to send a letter to the board for nuclear pharmacists, because we also have individuals in this situation?

DR. ZELAC: Absolutely This is Zelac. Absolutely. The working group that was addressing this petition, and everyone from that point on, up to the Commission, recognized there was potential for a broader issue here, and simply the groups that were addressed in the petition itself. So the intent is to look at this in the broader, more general sense, to all of the certified individuals in groups who might seek--whose members might seek authorization on medical use licenses--nuclear pharmacists, authorized users, medical physicists.

MR. MATTMULLER: Thank you.

DR. HOWE: This is Dr. Howe. I'd like to bring in a point, and that is I was active, working on the radiopharmacy rule back in 1992, and I'm not sure

the certified nuclear pharmacists are in the same category. We recognized them back in '92, and their criteria for selecting pharmacists to be board-certified have not changed, and the board itself was able to go back quite a ways, I think to its beginning inception, to say all of its board-certified members could be recognized.

DR. ZELAC: Excuse me. This is Zelac. That's exactly the point I'm trying to make, in that it depends on when the board process was recognized in terms of diplomates from that point forward being able to apply by the certification pathway. Some boards are potentially retroactive, well before the date when they actually made application for recognition, to their inception, as Dr. Howe has just pointed out.

MR. LIETO: This is Ralph Lieto. But the issue with the nuclear pharmacist, there's the concern regarding them being named as RSOs. That is a current issue, and this petition, you know, speaks to that problem of people who could not be put on licenses such as RSOs, and prior to the implementation dates that the Part 35 T&E rule applies to.

So there's some specific application to that group also, that would be affected.

DR. MALMUD: Thank you. My understanding

is that the letters will go out to each of the certifying boards.

DR. ZELAC: That is correct.

DR. MALMUD: Each will have its opportunity to comment and make recommendations and justifications.

DR. ZELAC: Also correct.

DR. MALMUD: In this case I gather the more information received, the more likely the response will be one that's in line with the recommendation.

Someone else wished to make a comment, I believe.

MR. MARTIN: Dr. Malmud, this is Melissa Martin with AAPM. I was just wondering, I'm active with, originally ACR, very active too. Do we have or can we get any time estimate that these letters will actually go out to the boards, so that this item doesn't just get tabled? Do we know when to expect to request the boards for action?

DR. MALMUD: I will ask Dr. Zelac, right now, when he anticipates those letters going out.

Dr. Zelac.

DR. ZELAC: While I have been chosen, so to speak, to act for the medical group, I'm not in a

position to make that determination, although I would expect that the intent would be expeditious production and sending of these letters.

DR. MALMUD: Expeditious is an adjective. Does it have a number of days associated with it? Or months?

DR. ZELAC: You have to ask someone else that.

DR. MALMUD: Who would we ask?

DR. ZELAC: Well, you could ask Cindy Flannery. Or you could ask Christian Einberg.

DR. MALMUD: Is either of those two with us now?

MS. FLANNERY: Yes. This is Cindy Flannery. I guess I'm kind of struggling with being able to really provide a timeline with this as well. You know, just brainstorming this morning on how we can gather information to provide rulemaking with a technical basis. So, you know, I'm not certain we could really give a timeframe.

I do know that I dearly would like to get the information and responses, you know, by the end of the year. So it's not something that we could, you know, really sit on for a long time.

DR. MALMUD: Thank you.

MR. LIETO: Dr. Malmud?

DR. MALMUD: Yes.

MR. LIETO: This is Ralph Lieto. I don't know if we need to make this as a motion, or simply maybe the chair could make it as a committee request.

Could we have identified who this medical group team is going to be composed of, addressing this specific issue? One. And number two, either some type of an outline of what this plan is intended to do to get this data? Cause I just have some reservations that a letter going to just boards is going to get the information that's needed.

And I guess thirdly, can we put this as an agenda item for progress reporting at the next meeting?

DR. MALMUD: With respect to your last recommendation, yes, we could put it as an item for progress report for the next meeting, and I'll ask Cindy to actually make certain that it's on the agenda.

With respect to the first two items, I can't address those. Is there someone who can, from the NRC staff?

MS. FLANNERY: This is Cindy Flannery. As far as the medical radiation safety team, it consists

of Ron Zelac, Donna-Beth Howe, Duane White, Ashley Tull, and myself. And I hope I'm not leaving anybody out. Was that Ralph who asked the question?

MR. LIETO: Yes; it was.

MS. FLANNERY: I guess, Ralph, we're open to other recommendations or ideas. You said that you're not certain whether, you know, that information would be what we needed. If you have some other suggestions, we're open. Like I said, we did some brainstorming this morning but we like to, you know, get any input from ACMUI as to how we could get this information that we can use for the technical basis.

MR. LIETO: Well, I don't want to speak for some of the general public members that are on line here, but I would that the academies or colleges of the professional groups involved would provide an avenue of information for members who, you know, might speak to, you know, this training and experience issue directly affecting them.

So I mean, you can identify the boards--the boards can identify the members who are certified and have an idea identified for potential candidates but it sounds like you want also some actually --

DR. MALMUD: This is Malmud. We're getting a lot of interference.

MS. TULL: This is Ashley. Whoever is calling from a cell phone, please press star six.

DR. MALMUD: Did someone join us?

Has someone moved to a mobile phone?

MS. FLANNERY: That's better now.

DR. MALMUD: Thank you.

All right. Please go ahead, Ralph. You were speaking.

MR. LIETO: Well, I would think that there might be other groups, such as the academies and colleges, whose members are board-certified, that might also provide information that would affect this issue, you know, other than just the boards.

DR. MALMUD: Can you give us an example of one.

MR. LIETO: Well, there's the American Academy of Health Physics. American College of Radiology. American College of Medical Physics.

DR. MALMUD: So you're suggesting--

MS. FAIROBENT: AAPM. SNM. ASTRO.

DR. MALMUD: So you would suggest that the letters go to those groups as well.

MS. FAIROBENT: ABHP.

MR. LIETO: Well, I would think that you would definitely want to consider some of those; yes.

DR. MALMUD: Your assumption is that they all have a database that's not available to the boards; is that correct?

MR. LIETO: Of board-certified members; yes.

DR. MALMUD: Yes. All right. We'll take that as a suggestion to NRC staff. Are you willing to send letters to them as well?

MS. FLANNERY: This is Cindy Flannery. We could do that but it's my understanding that a lot of these organizations are sort of associated or have sort of a relationship with these organizations and with the boards. So say, for example, the ABHP works closely with the AAHP. So I would think, you know--I guess I'm not certain that we would get more information from these organizations. But if you think that we could, that's a suggestion that, you know, we're open to.

DR. MALMUD: We are enthusiastic about the suggestion, since we don't believe that the boards will have some of the data that you are seeking.

MR. LIETO: This is Ralph Lieto again. I guess maybe, in answer to my second question or point, a request, that if we had an idea of what the, you know, sort of plan is here of getting the information

to address the petition questions, maybe that might be, you know, a better way for the committee members to respond to that, you know, to that specific point, as to whether they're appropriate groups or not.

But just kind of getting this thrown at us today, in generalities, it's kind of hard to respond as to whether they would--they might even be the better group to go to than the boards.

DR. MALMUD: So, in summary, then, we're suggesting that you also send the letters to those groups, and the additional data may be of value.

Is that a fair recommendation?

MR. LIETO: Yes.

DR. MALMUD: So that's our recommendation. We hope you'll be responsive to it.

May we move on to the next item? It's 3:25 and the meeting was to have ended at 3:00. So do you think we can cover the issue of the Yttrium-90 microspheres guidance clarification on the proctor for the three cases?

MS. TULL: Dr. Malmud, it's really your call. I have 3:15 right now and we do have this line until 3:30.

DR. MALMUD: Okay. I think we can.

MS. TULL: Okay. If not, then we can

schedule a second teleconference. It's up to you.

DR. MALMUD: We've agreed that the yttrium microspheres should have, be proctored for three cases, so that the new individuals will have had at least three hands-on experiences handling these.

The issue is with respect to who will proctor. Is that the question?

MS. TULL: This is Ashley. That's correct.

DR. MALMUD: And the proctors who certainly are approved, are physicians who have done these, but we recognize there are not enough physicians who have done these to be the proctors for all the trainees throughout the country, and therefore there are other proctors. And the question is who are the other proctors? Who shall they be?

MS. TULL: That's correct. And I believe we have both manufacturers on the line that can address this issue.

DR. MALMUD: And who are the manufacturers recommending for proctors?

MS. TULL: MDS Nordion and Sirtex.

DR. MALMUD: May we hear from one, and then the other. Would Sirtex.

MR. THURSTON: Yes. This is Ken Thurston

from Sirtex Medical.

DR. MALMUD: All right. Your recommendation for proctors is...?

MR. THURSTON: That in the event that an individual site requires training for a new user, ordinarily the three--a physician would be required to attend all three cases. In selected circumstances, sites have demonstrated to be very facile in terms of their ability to administer the product after, for example, two cases, and to be completely in line with our certification requirements.

There are also certified non-physician manufacturers' representatives who are trained in the radiation safety aspect of the procedure, that could proctor that third case, because the clinical requirements under a physician, where we're more concerned about where the catheter is placed in the delivery of the product are at issue, but once that issue's been resolved, it is the opinion that there's no reason that the radiation safety aspects could not be handled by a non-physician proctor. So that is the proposal on the table. That the third case could be proctored by a non-physician.

DR. MALMUD: So you're recommending two by a physician, a minimum of two by a physician and the

third could be by a physician also, but that in other cases, the third could be by a proctor from the manufacturer?

MR. THURSTON: Right, and those provisions have already been discussed under the simulated bench studies. Those actually are proctored by manufacturer's representatives. So yes, that is correct.

DR. MALMUD: Thank you.

MR. THURSTON: It would just mean that the requirement would be reduced, if in the judgment of the manufacturer, the clinical aspects of the procedure had been addressed in the first two cases.

DR. MALMUD: May we hear the recommendation of Nordion.

MR. BURNETT: This is Tom Burnett from MDS Nordion. I'd just like to clarify our training procedure which we described at the April meeting of the ACMUI.

DR. MALMUD: Yes.

MR. BURNETT: We actually offer a full day course that is put on by an authorized user and a team, where they cover all of the medical aspects of the procedure, including going through actual dosimetry for actual cases, where they go through

three simulations, procedure check lists, everything to do with the anatomy and medical concerns.

We follow that up, then, with three on-site supervisions for the initial three cases that the institution will go through, and for that we have, for seven years, used full-time employees of Nordion which have extensive training in areas such as radiation safety, sterile techniques, direct working experience in radiation and sterile environments. Attendance at TSU, which is our university. Direct product training which is extensive. And so on.

All of this has been very well-received by centers to this point, and the questions and issues that come up are to do the actual use of the kit once you get into the on-site supervision of the three cases, because the medical aspects have been dealt with in a sense.

DR. MALMUD: Could you answer a question for me, please. MDS Nordion. Do you require three hands-on supervisions within this program?

MR. BURNETT: We do three simulations as per the discussion we had at the April 29th meeting. That is done under an AU supervision --

DR. MALMUD: I understood that. My question was how many hands-on supervisions of actual

patients?

MR. BURNETT: Of actual patients, we do a minimum of three, but we don't limit it to three. We will go until we're comfortable the center is adequate to do the procedure by themselves.

DR. MALMUD: So the common thread in both approaches is three clinical cases?

MR. BURNETT: Yes.

DR. NAG: I have a question for the manufacturer. The question is on site, right now, how many cases are you proctoring by an MD versus how many are you proctoring by a representative from your company? I'm not talking about the simulation cases in the university.

MR. BURNETT: On site, right now, we use full-time Nordion employees. We do not use part-time contracted MDs. We feel this gives us much better quality control over the consistency of the information conveyed to the center, and more than sufficient experience with the kit. Often the individuals were involved in the development of the kits. So they really understand, in depth, what issues may happen and how to deal with them appropriately.

DR. MALMUD: So this is Malmud. In

summary, then, the Sirtex approach is three supervisions, a minimum of two of which must be with a physician, the third by a representative of the company.

And the Nordion approach is a day's symposium plus three cases which would be supervised by a Nordion employee. Is that correct?

MR. BURNETT: That's correct.

DR. MALMUD: Okay. Now having heard those two summaries, are there questions?

Is there a motion to approve these two approaches?

I couldn't hear. Who said something? I'm sorry. Someone said something.

DR. NAG: I think that someone else is on a speaker-phone or something. This is Dr. Nag.

DR. MALMUD: Yes, Dr. Nag?

DR. NAG: I think what we need to ensure is two things. One is the medical decision about the catheter placement, and the second is about connection of the bottles and catheters and radiation safety. They are two slightly different items that need to be learned, and that could be fulfilled in a number of different ways.

So I think we should make our rules

flexible enough that these two items are at play. The medical portion obviously has to be addressed by an MD, or by the person, an authorized user basically, as well as the connections and radiation safety would be handled by a manufacturer's representative.

And therefore it's not whether MD Nordion shows up or a person shows up. We have to write our rules such that both of these are addressed, so we can make it a generic statement that they have these two trainings and we do not need, necessarily, to say that it has to be by an MD or by a representative.

DR. MALMUD: Thank you, Dr. Nag.

Are there other comments with regard to this?

MS. GILLEY: Debbie Gilley.

DR. MALMUD: Yes, Debbie Gilley?

MS. GILLEY: I have one comment to make and that is how we are going to, in the Agreement States, identify those people who have completed the treatment, completed the preceptoring yet have not done the clinical treatment, and how do you approach that type of activity? And I'm looking for guidance to see how NRC is going to handle it.

MS. TULL: This is Ashley. If I understand your question correctly, that's addressed

in the draft guidance, right now, that was sent to ACMUI, I'm going to say the beginning of July.

DR. MALMUD: Yes.

MS. TULL: That was addressed in there. It would be a notification type procedure. I don't want to confuse that with 10 CFR 35.14. But once the proctored cases were completed, it could simply be a letter saying three proctored cases have been completed, and you put that on file. We didn't want to require a license amendment due to administrative burden and timelines.

MS. GILLEY: But you need a license amendment in order to possess these radioactive materials. So you're going to have to have some documentation that you have qualified, authorized users, before you can put these items on license. Is that not correct?

MS. TULL: This is Ashley again. You would be an AU when you complete your three simulated cases. You would be put on the license and authorized for the materials, using a license amendment, with the promise to get three proctored cases. So now you're an AU. Then after you do your three proctored cases, you send a letter in, just notification that it's complete.

MS. GILLEY: In the event we have a medical misadministration on those proctored cases, a Medical Event on those proctored cases, how does that set well with NRC?

DR. HOWE: They're an AU and they're --

[Simultaneous conversation]

We've had many Medical Events with they see us on the very first patient. Dr. Howe, NRC.

DR. MALMUD: Does that answer your question, Ms. Gilley?

MS. GILLEY: Yes, sir.

DR. MALMUD: Thank you.

MR. THURSTON: This is Ken Thurston from Sirtex. I'd just like to make a comment. In the event that a Medical Event did occur during those first three cases, that would then impact the number of cases that we would then continue to proctor on. So the minimum may be two cases, in the case of sites that demonstrate very, very good technique. In those cases where sites do not, we continue to go back and proctor. We will not necessarily check a limited two for every site. It will depend on how well the site demonstrates their capabilities.

MS. GILLEY: This is Debbie Gilley again. To get that straight, I don't have a relationship with

the manufacturer. My relationship is with the licensee.

MR. THURSTON: Yes. I understand.

MS. GILLEY: Thank you.

DR. MALMUD: Any other questions?

[No response]

DR. MALMUD: So Dr. Nag's recommendation was that we be concerned about two elements. One was the medical placement of the catheter and the other was the radiation safety issue.

My understanding is that the catheter is really directed by the interventional radiologist. Is that not the case?

DR. NAG: It is done by the interventional radiologist in many sites with, in close cooperation with the radiation oncologist, and in other cases without. But the primary responsibility is the interventional radiologist.

DR. MALMUD: Yes. It's the interventional radiologist who places the catheter, and this is something they do on a daily basis without radioactive material. So the issue therefore is not the competence of the interventional radiologist in placing the catheter. It's in the decision as to where the catheter should be placed and whether or not

the initial tracer dose of the MAA has been calculated with respect to the percentage of material that's shunting and therefore calculating the right dose.

DR. NAG: And whether it's going in the right place, whether is a backflow, how much are you going to push, when do you--to make a decision when to stop. Yes. Those are the portions that have to be the medical decisions.

DR. MALMUD: Right. And those are under the direction either of the nuclear medicine physician, as they are here, or the physicist, or I imagine in some institutions, the radiation oncologist.

MS. TULL: Dr. Malmud, this is Ashley.

DR. MALMUD: Yes?

MS. TULL: I just wanted to note that it is now 3:30.

DR. MALMUD: Yes. What do you recommend we do? Have another conference call?

MS. TULL: We can do that.

DR. MALMUD: I would--

[Simultaneous conversation]

MS. TULL: If the committee is ready to say what's acceptable, the current practice, two of three cases by an MD, three of three cases by an MD. If the

committee can make a statement, we can go on the record and move forward with the guidance, or we can postpone it.

DR. MALMUD: Well, if I may, I'll try and make a motion and see if we can get it seconded, and either rejected or carried through.

And that is that we accept the recommendations of both groups, the group that is using the three cases, two of which are by a physician, the third by a representative of the company, and the other recommendation is the course followed by three cases which may be done by representatives of the company.

In both instances, there are many examples of introduction of new technologies by both of these techniques in medicine, and therefore these are not unusual approaches by either manufacturer.

I'm experiencing one here at Temple. I've done two cases using one of those systems and I found that it is very instructive. These are live cases, and non-simulation. So I can't speak to the simulation. However, the presentation that we heard with respect to the simulation of course was very impressive.

So I would make a motion that we accept

both approaches since they incorporate the concerns with regard to radiation safety and clinical expertise. That's a motion.

DR. VETTER: This is Ralph Vetter. I second that motion.

DR. MALMUD: It's been seconded. Discussion. If there's--

MR. LIETO: This is Ralph Lieto. The issue is whether you're not going to have physician proctoring with a hands-on or you are. It was my interpretation of the original question from NRC staff, about who the proctor can be.

MS. TULL: This is Ashley. That's correct, Mr. Lieto.

DR. MALMUD: That's correct.

MR. LIETO: So what you're saying is you have a hodge-podge, and in which case no physician proctoring is acceptable?

DR. MALMUD: I have not used the term "hodge-podge." There are more than a few examples of representatives of manufacturers entering the operating room and being much more expert at the technique than any physician in the operating room in the introduction of a new technique, whether it's an implant or some other methodology.

So I'm not hostile to the approach recommended by one of the manufacturers, nor am I hostile to the approach used by the other.

I listened to every word that was said at the presentation of the manufacturers to the ACMUI, and I'm personally satisfied, but my personal satisfaction should not extend to the committee. The committee should make its own decision.

So I've made the motion with respect to my own observations and experience, hoping that the committee will decide yea or nay. If it's nay, we'll bump it to another meeting. Is that fair?

DR. NAG: I think we haven't had enough time to see how that wording would be--my preference was that we have it worded in such a way that it will apply to both, the method. Basically saying that we need a proctor who doesn't have to be, say, whether it's MD or representative, but we need to have proctors that will oversee the different components, including the catheter placement, and radiation safety and connections. So these are the parts that have to be processed, and, you know, we don't need to say whether it's an MD or whoever is proctoring it.

For example, the catheter placement would be an MD but the radiation safety proctoring could or

could not be an MD.

DR. MALMUD: I understand your point, but I also understand that an MD being present, who is not an interventional radiologist, offers very little by way of anatomical expertise to that which the interventional radiologist is doing.

DR. NAG: Right.

DR. MALMUD: Whether he had an MD, a PhD, or no degree at all. So my feeling is that the placement of the catheter is clearly the "turf" of and represents the experience and training of the interventional radiologist. He or she is always present for the case. They can't do it without the interventional radiologist.

DR. NAG: But again it has to be proctored with an interventional--who has knowledge of interventional radiology, and the blood flow and what radioactive material needs to go to which portion. So that's why not just say MD or not MD. It has to be someone knowledgeable about the case.

DR. MALMUD: And perhaps your wording would be an amendment to my recommendation, which is that there be present, whichever method is used, that there be present both the expertise of the interventional radiologist and the expertise of the

individual who is knowledgeable of and has experience with the use of injectable non-sealed sources.

DR. NAG: Right.

DR. MALMUD: Is that an acceptable motion, Dr. Nag?

DR. NAG: Yes. Not in someone who has knowledge of the interventional techniques, because in some places it may not be an interventional radiologist, could be a--you know--could be--I know in certain cases the radiation oncologist is so knowledgeable, that he--you do not want to prevent--there has to be the knowledge, not, you know, what his label is.

DR. MALMUD: This is Malmud again asking Nag a question. Dr. Nag, are there radiation oncologists who do this themselves, without an interventional radiologist?

DR. NAG: No, but there are proctors who are radiation oncologists, and MD candidates from what I know off hand who have more knowledge that in the blood flow, and when to stop, and when to go, that he directs the radiation--the interventional radiologist, you know, when to stop and when to go, and whether to go further, and so forth.

DR. MALMUD: Okay. Thank you.

DR. NAG: And, you know, similar like. If I'm working with an interventional radiologist who hasn't done this before, I tell them, you know, when to go and when to stop. You know, it's the knowledge that's important, not your label, whether you're an MD or whether you are interventional radiologist or radiation oncologist.

I wanted that wording in there for the catheter placement, and radiation safety, and the connection.

DR. MALMUD: So Dr. Nag's motion would amend mine to be reworded as that whichever technique is used, that there be present for the first three cases, at least, individuals with the knowledge, skill and training in both placement of the catheter, the calculation of the dose, and the methodology of injection.

DR. NAG: Radiation safety.

DR. MALMUD: And radiation safety.

Is that your motion?

DR. NAG: Yes.

DR. MALMUD: I withdraw mine and will second yours.

DR. SALEM: Dr. Malmud, this is Riad Salem listening in. If I could say just a few things. You

know, there are just a few issues with that. You know, this human being that has all of these skills, in the context of what everybody's describing here as their training program and their proctoring program, doesn't really exist.

There are a few individuals that have all of the skill sets that Dr. Nag has just described, and so, for example, with the Sirtex model, that third person is not a physician and so does not have the catheter position skills. He might have the radiation safety skills but not the catheter position skills, versus with the Nordion model they have the radiation safety skills but they are not interventional radiologists.

DR. MALMUD: Doctor, excuse me, you're correct, but I don't think that Dr. Nag was suggesting that all these skills belong to one person.

He said that these should be present.

DR. SALEM: But it seems like with that phrasing, it seems that you end up needing to have more people there for the actual initial proctoring session. So if you're not an Authorized User yet, which is what the proctoring portion is all about--

DR. MALMUD: Right.

DR. SALEM: Then you need to have

potentially, an interventional radiologist and a physicist or someone else to complement whatever the interventional radiologist or radiation oncologist, both skills they don't have. In fact you may be increasing the number of people that are required with that wording.

DR. MALMUD: Are you in favor of that or opposed to it?

DR. SALEM: I'm opposed to it. I'm actually in favor of the recommendations that have been made already. These have been models that have been tested and vetted for years, and have been working quite well. I think it's a small community, this community, and the two models, as you have seen yourself, Dr. Malmud, at Temple, they're pretty good models and they work, and the more terminology we add, the more I have seen where the sites now get confused because they follow the guidance, and they look at every word, and then, you know, sort of some questions will be raised as to whether this person has satisfied all these criteria.

DR. MALMUD: So you're more in favor of the motion than I made initially?

DR. SALEM: Yes, sir.

DR. VETTER: This is Dick Vetter. I also

have. I'm a little worried that the motion that's currently on the floor could be misinterpreted. So, for example, you have to have someone in the room who has radiation safety skills. The way I would interpret that is that includes everyone who is currently in the room, but I'm worried it would be interpreted that you now need a radiation safety expert, you know, the RSO or someone there. So I like the original motion better.

DR. NAG: Okay. I withdraw my motion. I mean, we all want the same thing but I don't think we have enough time to be saying, you know, how do we word this or that our intention is correctly forwarded in the guidance.

DR. MALMUD: Well, my motion was meant to approve of both techniques that are currently in use, both out of MDS Nordion and of Sirtex, because they both mimic models that have been used successfully before, and are continuing to be used in other fields as well. And therefore I thought if we simply gave them both our blessing we could move forward with this.

DR. NAG: That's fine.

DR. MALMUD: So if I may, with your permission, Dr. Nag, I'll keep my motion on the floor.

DR. NAG: That's fine.

DR. MALMUD: May we call the vote. All in favor?

[Chorus of ayes]

DR. MALMUD: Any opposed?

MS. GILLEY: This is Debbie Gilley. I oppose.

DR. MALMUD: Debbie Gilley opposes. Any abstentions?

[No response]

DR. MALMUD: It carries with a majority of the committee.

DR. NAG: Debbie, would you clarify why you're opposing. I mean, I would like to know.

MS. GILLEY: I don't see this technology any different than intravascular brachytherapy, and I think we had no problems at all getting the appropriate clinical cases done with the appropriate authorized users this way, and I just feel that it's very important that we have that, and I also am concerned about documentation for the Agreement States, to make sure that the appropriate documentation, this person is qualified before they're put on a license. Thank you.

DR. MALMUD: Thank you, Debbie Gilley.

What both groups require is that when the individuals have completed three cases, that there be a letter certifying that they have completed active participation in three cases with patients before they would be, have fulfilled the requirements.

MS. GILLEY: This is Debbie Gilley again. I'm not inclined to add possession of this material on to a license until I have an authorized user who is qualified. Thank you.

DR. MALMUD: Thank you, Debbie.

So we've heard both the wishes of the majority of the committee and the comments of the sole dissenter.

Are there any other--I'm sorry?

MR. LIETO: I don't think you heard my opposition. I voted "no" too.

DR. MALMUD: Oh, I'm sorry.

MR. LIETO: I think I got drowned out.

DR. MALMUD: Who is speaking?

MR. LIETO: This is Ralph Lieto. I'm sorry.

DR. MALMUD: Ralph. I'm sorry.

MR. LIETO: So there are two opposition votes.

DR. MALMUD: There are two oppositions.

Thank you.

DR. THOMADSEN: Mr. Chairman, this is Thomadsen. Can I ask Ralph for the rationale for his dissent?

DR. MALMUD: You may but this is the chairman, and I am already 40 minutes late for my other appointment, so I--

MR. LIETO: Bruce, I'll be glad to call you and let you know.

DR. MALMUD: Thank you.

Is there a motion for adjournment?

MS. TULL: As long as you need the line, the line is available.

DR. VETTER: I move that the meeting be adjourned.

DR. MALMUD: Thank you, Dr. Vetter.

MR. LIETO: I would second.

DR. MALMUD: And thank you all for your patience and participation, and members of the public as well. Thank you.

[Whereupon, at 3:42 p.m., the meeting was adjourned]