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1 UNITED STATES OF AMERICA

2 NUCLEAR REGULATORY COMMISSION

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4 ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

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6 MEETING

7 + + + + +

8 TELECONFERENCE

9 + + + + +

10 MONDAY,

11 JULY 21, 2008

12 + + + + +

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

16 COMMITTEE MEMBERS PRESENT:

17 LEON S. MALMUD, M.D., Chairman

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

19 DOUGLAS F. EGGLI, M.D., Member

20 DARREL R. FISHER, Ph.D., Member

21 DEBBIE B. GILLEY, Member

22 RALPH P. LIETO, Member

23 STEVEN R. MATTMULLER, Member

24 SUBIR NAG, M.D., Member

25 SALLY SCHWARZ, Member

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1 BRUCE R. THOMADSEN, Ph.D., Member

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

3 JAMES S. WELSH, M.D., Member

4
5 COMMITTEE MEMBERS NOT PRESENT:

6 ORHAN H. SULEIMAN, Ph.D., Member

7
8 NRC STAFF PRESENT:

9 Jacqueline "Jackie" D. Cook

10 Christian "Chris" E. Einberg

11 Cynthia "Cindy" M. Flannery

12 Sandra "Sandy" L. Gabriel

13 Donna-Beth Howe, Ph.D.

14 Penny A. Lanzisera

15 Sophie Le

16 Robert "Rob" J. Lewis

17 Edward "Ed" M. Lohr

18 John R. Madera

19 Alexis Sotomayor-Rivera

20 Ashley M. Tull

21 Duane E. White

22 Jackie "Jack" E. Whitten

23 Ronald "Ron" E. Zelac

24

25

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1 ALSO PRESENT:

2 Dean Broga

3 Tom Burnett, MDS Nordion

4 Ann Warbick Cerone, MDS Nordion

5 Brian Erasmus, MDS Nordion

6 Sandor Erdelyi, SIRTEX

7 Lynne Fairobent, AAPM

8 Emily Gardner, ASNC

9 Melissa Martin, AAPM

10 Richard Martin, ASTRO

11 Jacob Ninni, RSO, Rhode Island Hospital

12 Mike Peters, ACR

13 Doug Pfeiffer

14 Amanda Potter, AAPM

15 Riad Salem, MDS Nordion

16 Ken Thurston, SIRTEX

17 Cindy Tomlinson, SNM

18 Gerald White, AAPM

19

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

15 MR. EINBERG: Occasional.

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

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

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

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

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

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

25 The ACMUI comments on fingerprinting. We

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

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

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

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

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

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

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

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

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

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

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

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

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

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1 went to the rulemaking section.

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

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

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

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

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

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

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

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

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

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1 things do happen.

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

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

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

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

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

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

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

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

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

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

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1 DR. VETTER: Okay. Thank you, Dr. Nag.
2 This is Dick Vetter. At least two members
3 of the committee did respond with comments that they
4 shared with everyone. That was Dr. Thomadsen and Dr.
5 Mattmuller. Would either of you have any comments on
6 this issue at this time?

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

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

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

16 DR. VETTER: Steve Mattmuller, any
17 comments?

18 [No response]

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

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

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

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

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

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

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1 rulemaking division director and a regional director.

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

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

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

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

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

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

10 That's very common in a proposed rule.

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

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

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

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

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

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

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

22 Dr. NAG: Can I ask for a clarification.

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

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

5 MR. LEWIS: No. The rule would not be
6 effective until there's a final rule. So from the
7 date the Commission says to publish a proposed rule
8 for comment, we would issue a public comment period,
9 which is normally about 75 days, some rules, it can be
10 90 if it has NAFTA implications, for example, they're
11 ninety. This one probably wouldn't.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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1 delay things quite a bit for this rule.

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

10 Most of the time--

11 [Simultaneous conversation]

12 MR. LEWIS: Dr. Nag.

13 DR. NAG: Yes.

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

18 DR. NAG: Okay.

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

25 DR. NAG: Right. But basically, the ASTRO

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

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

8 DR. WELSH: Yes. This is Jim Welsh.

9 DR. VETTER: Yes?

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

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

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

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1 longer. A month or two.

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

5 MR. LEWIS: 75 days.

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

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

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

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

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

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

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

23 DR. NAG: Yes; right.

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

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

3 DR. VETTER: Please identify yourself.

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

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

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

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

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

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

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

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

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

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

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

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1 MR. LIETO: Question.

2 MR. LEWIS: Yes. Question by someone?

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

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

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

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

5 Does this incorporate those comments?

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

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

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1 manner, to be sure that this was the intent.

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

6 MR. LIETO: Okay.

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

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

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

25 DR. VETTER: This is Dick Vetter. We are

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

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

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

19 DR. VETTER: Thank you. Any other
20 comments?

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

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1 the conference call.

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

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

12 DR. ZELAC: Dr. Vetter.

13 DR. VETTER: Yes?

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

15 DR. VETTER: Yes?

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

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

25 DR. ZELAC: Certainly.

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1 DR. VETTER: Yes.

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

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

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

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

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

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

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

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

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

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

21 DR. MALMUD: I was not.

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

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

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

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

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

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

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

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

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

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

22 DR. MALMUD: Thank you, Dr. Zelac.

23 Dr. Vetter.

24 DR. VETTER: Yes?

25 DR. MALMUD: Do you recall? Was that the

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1 intent of the ACMUI?

2 DR. VETTER: I think it was at the time,
3 but I'm not sure that we understood the implications
4 that Dr. Nag has currently outlined relative to, you
5 know, seeds--that's the correct word. As he
6 mentioned, when you're withdrawing the implant device--
7 -

8 DR. MALMUD: Yes.

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

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

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

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

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

10 DR. MALMUD: Yes.

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

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

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

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

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

10 How are you going to know a seed that was
11 3 cm away? Was it placed there or was it placed into
12 the target tissue, and when you are pulling your
13 needle back it ended up there? That would be
14 difficult to, or impossible to know, and therefore my
15 suggestion was that we know that a few seeds to end up
16 more than 3 cm away, and we make allowance for that,
17 because a few seeds outside, it doesn't matter whether
18 you call it a Medical Event or not. It's not a
19 problem. And we know that in the lung that happens
20 all the time, and we know it's not a problem. And so
21 we make allowance for that.

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

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

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

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

17 So what we are trying to distinguish is
18 whether it was just a few odd seeds that are more than
19 3 cm away as opposed to a whole bunch of seeds that
20 were placed either in the bladder, or, you know, way
21 down in the perineum, and that was the reason for
22 making up some of the rule change, to detect a gross
23 error, not a few seeds coming loose. And I think this
24 is where the NRC fails to distinguish what we were
25 trying to do.

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

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

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

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

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

3 DR. MALMUD: Yes.

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

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

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

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1 us.

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

6 DR. NAG: Yes; there was.

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

11 DR. NAG: Yes.

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

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

19 DR. VETTER: Okay.

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

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

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

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

9 DR. NAG: I have a question.

10 DR. MALMUD: Oh. Go ahead.

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

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

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

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

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

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

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

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

10 Am I correct in making that assumption of
11 the NRC?

12 DR. NAG: I agree with you.

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

18 DR. NAG: I agree with you, and again my
19 concern is that there is a 75 day public commentary
20 period. We may not be able to come up with a number
21 because trying to get a meeting of a lot of people
22 takes time, and then to get an agreement, whether it's
23 5, 10, 15 or 20 percent, will take a lot more time,
24 and, you know, my reasoning therefore was to say let's
25 take this back, send to the Commissioners a correct

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1 statement of what we really meant.

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

4 DR. NAG: Right.

5 DR. MALMUD: Dr. Welsh.

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

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

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

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

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

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

4 DR. MALMUD: Yes.

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

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

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

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

25 If we're going to have to provide some

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

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

17 MR. LIETO: So move.

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

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

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

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

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

5 MR. LIETO: Yes.

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

8 Any further discussion?

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

12 DR. MALMUD: Dr. Nag.

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

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

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

19 DR. MALMUD: Yes?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

17 MR. LEWIS: Of course.

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

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

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1 DR. VETTER: Okay.

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

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

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

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

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

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

6 DR. MALMUD: Yes.

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

9 DR. MALMUD: Yes.

10 DR. NAG: Yes; that's possible.

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

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

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

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

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

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1 that be acceptable to the parties who are interested?

2 Dr. Nag, Dr. Welsh, Dr. Vetter, Mr. Lieto?

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

5 DR. NAG: Dr. Thomadsen also.

6 MR. LIETO: And I would too.

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

15 Within the next two weeks?

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

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

22 DR. NAG: I will.

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

25 [Chorus of yeses]

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

3 [Chorus of ayes]

4 DR. MALMUD: Any nays?

5 DR. NAG: Nay.

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

8 [No response]

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

15 DR. ZELAC: Dr. Malmud.

16 DR. MALMUD: Yes, Dr. Zelac?

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

20 DR. MALMUD: Please do.

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

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

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

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

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

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

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

5 May we move on?

6 DR. VETTER: Yes.

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

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

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

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

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

25 DR. MALMUD: You can certainly make such a

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1 motion as a form of a request to the NRC.

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

4 DR. WELSH: I second it.

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

6 DR. WELSH: Jim Welsh here.

7 DR. MALMUD: Dr. Welsh seconds the motion.

8 Is there any discussion of the motion?

9 [No response]

10 DR. MALMUD: All in favor of the motion?

11 [Chorus of ayes]

12 DR. MALMUD: Any opposed to the motion?

13 [No response]

14 DR. MALMUD: Any abstentions?

15 [No response]

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

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

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

24 DR. MALMUD: Who wishes to address the
25 subject?

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

3 DR. MALMUD: Yes.

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

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

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

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1 understood.

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

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

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

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

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

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

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1 DR. ZELAC: Dr. Malmud.

2 DR. MALMUD: Dr. Zelac.

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

6 DR. MALMUD: Thank you.

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

17 And those letters will solicit information
18 on the numbers of actors, individuals, who are
19 certified prior to the recognition of a board process.

20 As I said, most of those that were listed in Subpart
21 J have, at this point in time, been recognized, re-
22 cognized, if you will, by NRC or Agreement States.
23 A couple are still pending.

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

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

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

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

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

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

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

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

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

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

9 MR. LEWIS: Dr. Malmud. No.

10 DR. ZELAC: --to gather this information.

11 MR. LEWIS: Dr. Malmud.

12 DR. MALMUD: Yes?

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

18 DR. MALMUD: Yes.

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

22 DR. MALMUD: Thank you.

23 Dr. Zelac?

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

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1 individuals might have.

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

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

6 DR. MALMUD: Please do.

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

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

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

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

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

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

13 [Simultaneous conversation]

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

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

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

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

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

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

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

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

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

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

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

3 DR. VETTER: Go ahead, Jerry.

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

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

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

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

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

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

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

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

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

13 DR. MALMUD: Okay.

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

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

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

4 MR. WHITE: Thank you.

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

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

9 DR. MALMUD: Thank you.

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

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

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

25 DR. ZELAC: That is correct.

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

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

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

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

22 MR. MATTMULLER: Thank you.

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

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

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

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

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

25 DR. MALMUD: Thank you. My understanding

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

3 DR. ZELAC: That is correct.

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

7 DR. ZELAC: Also correct.

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

12 Someone else wished to make a comment, I
13 believe.

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

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

23 Dr. Zelac.

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

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

4 DR. MALMUD: Expeditious is an adjective.

5 Does it have a number of days associated with it? Or
6 months?

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

9 DR. MALMUD: Who would we ask?

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

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

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

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

25 DR. MALMUD: Thank you.

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1 MR. LIETO: Dr. Malmud?

2 DR. MALMUD: Yes.

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

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

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

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

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

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

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

4 MR. LIETO: Yes; it was.

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

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

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

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

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

3 DR. MALMUD: Did someone join us?
4 Has someone moved to a mobile phone?

5 MS. FLANNERY: That's better now.

6 DR. MALMUD: Thank you.

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

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

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

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

19 DR. MALMUD: So you're suggesting--

20 MS. FAIROBENT: AAPM. SNM. ASTRO.

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

23 MS. FAIROBENT: ABHP.

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

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

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

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

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

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

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

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

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

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

12 Is that a fair recommendation?

13 MR. LIETO: Yes.

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

16 May we move on to the next item? It's
17 3:25 and the meeting was to have ended at 3:00. So do
18 you think we can cover the issue of the Yttrium-90
19 microspheres guidance clarification on the proctor for
20 the three cases?

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

24 DR. MALMUD: Okay. I think we can.

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

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

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

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

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

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

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

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

22 MS. TULL: MDS Nordion and Sirtex.

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

25 MR. THURSTON: Yes. This is Ken Thurston

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1 from Sirtex Medical.

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

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

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

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

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

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

9 DR. MALMUD: Thank you.

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

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

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

20 DR. MALMUD: Yes.

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

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

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

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

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

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

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

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1 patients?

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

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

8 MR. BURNETT: Yes.

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

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

25 DR. MALMUD: So this is Malmud. In

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

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

8 MR. BURNETT: That's correct.

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

11 Is there a motion to approve these two
12 approaches?

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

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

17 DR. MALMUD: Yes, Dr. Nag?

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

25 So I think we should make our rules

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

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

12 DR. MALMUD: Thank you, Dr. Nag.

13 Are there other comments with regard to
14 this?

15 MS. GILLEY: Debbie Gilley.

16 DR. MALMUD: Yes, Debbie Gilley?

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

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

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

3 DR. MALMUD: Yes.

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

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

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

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

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

6 [Simultaneous conversation]

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

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

11 MS. GILLEY: Yes, sir.

12 DR. MALMUD: Thank you.

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

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

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1 the manufacturer. My relationship is with the
2 licensee.

3 MR. THURSTON: Yes. I understand.

4 MS. GILLEY: Thank you.

5 DR. MALMUD: Any other questions?

6 [No response]

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

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

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

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

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

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

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

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

15 DR. MALMUD: Yes?

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

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

20 MS. TULL: We can do that.

21 DR. MALMUD: I would--

22 [Simultaneous conversation]

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

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

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

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

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

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

25 So I would make a motion that we accept

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

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

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

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

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

15 DR. MALMUD: That's correct.

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

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

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

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

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

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

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

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1 could not be an MD.

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

7 DR. NAG: Right.

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

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

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

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

3 DR. NAG: Right.

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

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

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

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

25 DR. MALMUD: Okay. Thank you.

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

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

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

18 DR. NAG: Radiation safety.

19 DR. MALMUD: And radiation safety.

20 Is that your motion?

21 DR. NAG: Yes.

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

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

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

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

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

18 He said that these should be present.

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

24 DR. MALMUD: Right.

25 DR. SALEM: Then you need to have

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

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

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

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

24 DR. SALEM: Yes, sir.

25 DR. VETTER: This is Dick Vetter. I also

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

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

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

23 DR. NAG: That's fine.

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

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1 DR. NAG: That's fine.

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

4 [Chorus of ayes]

5 DR. MALMUD: Any opposed?

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

8 DR. MALMUD: Debbie Gilley opposes. Any
9 abstentions?

10 [No response]

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

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

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

25 DR. MALMUD: Thank you, Debbie Gilley.

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

6 MS. GILLEY: This is Debbie Gilley again.

7 I'm not inclined to add possession of this material
8 on to a license until I have an authorized user who is
9 qualified. Thank you.

10 DR. MALMUD: Thank you, Debbie.

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

14 Are there any other--I'm sorry?

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

17 DR. MALMUD: Oh, I'm sorry.

18 MR. LIETO: I think I got drowned out.

19 DR. MALMUD: Who is speaking?

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

22 DR. MALMUD: Ralph. I'm sorry.

23 MR. LIETO: So there are two opposition
24 votes.

25 DR. MALMUD: There are two oppositions.

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1 Thank you.

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

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

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

10 DR. MALMUD: Thank you.

11 Is there a motion for adjournment?

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

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

16 DR. MALMUD: Thank you, Dr. Vetter.

17 MR. LIETO: I would second.

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

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

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