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UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

MEETING

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Wednesday, June 13, 2007

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The meeting came to order at 8:00 a.m. in room T2B3 of Two White Flint North. Leon S. Malmud, MD, Chair, Presiding.

MEMBERS PRESENT:

Leon S. Malmud, MD Chairman

William Van Decker, MD

Douglas F. Eggli, MD

Ralph P. Lieto

Subir Nag, MD

Sally W. Schwarz

Orhan H. Suleiman, PhD

Jeffrey Williamson, PhD

Bruce Thomadsen, PhD

James Welsh, MD

Darrell Fisher, PhD

Debbie Gilley

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1 NRC STAFF PRESENT:

2 Sandra Wastler, Designated Federal Officer

3 Cindy Flannery. Alternate Federal Officer

4 Angela McIntosh

5 Ashley Tull

6 Donna-Beth Howe, PhD

7 Mohammad Saba

8 Duane White

9 Ron Zelac, PhD

10 ALSO PRESENT:

11 Gerald White

12 Dean Broga

13 Lynne Fairobent

14 Ann Warbick Cerone

15 Doug Pfeiffer

16 Ken Thurston

17 Armin Ansari

18 Luba Katz

19 Mike Peters

20 Gloria Romanelli

21 Craig Reed

22 Bill Metzger

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

8:14 a.m.

CHAIR MALMUD: Good morning, everybody.
We'll begin a very lengthy agenda today with the
presentation by Donna-Beth Howe on potential changes
to 10 CFR Part 35.

Dr. Howe?

DR. HOWE: Thank you, Dr. Malmud.

You'll see the very first thing is the
title of this presentation. It is "potential changes."
It is not proposed rulemaking. The process at the NRC
is that we develop what we call a user need memo that
identifies things that we think may need changes in
the rule. And this is going to be an attachment to a
user need memo that goes over to our rulemaking group.

So you're given a very early opportunity
to see if you agree with what the Staff's finding is
that we believe we need a change in the rules to fix
some of these problems.

You actually have two things in front of
you for the ACMUI members and there are extra copies
in the back. One is a more detailed verbiage of the
potential changes.

To put things on a slide in many cases I
had to abbreviate and condense and so you have a

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1 condensed version of the slides. And I've ordered
2 these in order of how they appear in the 10 CFR Part
3 35.

4 The very first issue comes from the
5 definitions in 35.2. When we looked at the definition
6 of the RSO, our general counsel has decided that if
7 you meet the definition of an RSO, you are an RSO.
8 And unlike other authorized individuals that can use
9 the notification process, the RSO normally is not
10 recognized on a license until they're reviewed by the
11 NRC.

12 So in the definition the board
13 certification pathway for the RSO is essentially a
14 definition of a RSO. And that carries onto the fact
15 that if you look in 35.50 and the preceptor statements
16 and the supervised work experience, that's under the
17 direction of an RSO. And OGC has determined that
18 since an RSO is defined in 35.2, that this work can be
19 done under the supervision of someone that is board
20 certified, meets the board certification route but is
21 not actually listed on a license as an RSO. And our
22 question to the ACMUI is is that your intent. We
23 don't believe that was the intent when we wrote the
24 rule, but that is one of the consequences.

25 I'm looking for comments.

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1 CHAIR MALMUD: Oh. Are there comments?

2 MEMBER VAN DECKER: Can you rephrase the
3 question?

4 DR. HOWE: Normally when we have a
5 preceptor or a preceptor attestation, the person that
6 is precepting or providing the supervised work
7 experience is an authorized individual, an authorized
8 user, an authorized medical physicist because they're
9 listed on a license or they meet all the criteria.

10 For the radiation safety officer we don't
11 identify radiation safety officers except on a
12 license, so you don't have the notification process.
13 So what we have is an interpretation that if you're
14 board certified in health physics or one of the
15 medical physics and you have your attestation that you
16 can function independently as an RSO, you're now
17 eligible to work as a supervising RSO or as a
18 preceptor RSO for someone else.

19 We think the intent of the rule was to
20 have someone actually functioning in that position
21 versus someone that met the criteria.

22 MEMBER NAG: The problem is that we are
23 already having something or people who can function as
24 an RSO. If you have dose rate that the person who
25 already has been RSO analyzes many of the smallest --

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1 you'll have problems trying to meet that.

2 RSO is someone who don't know what it is
3 to be analyzing. They need to know the -- you know,
4 the rules and they need to know what the problems are
5 which would have been met anyway. That's why it's my
6 personal feeling that they don't have to be analyses.

7 MEMBER SCHWARZ: Ralph, I would think you
8 would have an opinion on this.

9 MEMBER LIETO: Well, yes. I am probably
10 going to talk about this in my talk a little bit next.
11 But I'm still trying to understand the question that's
12 being asked. I'm --

13 MS. WASTLER: I think maybe if you look at
14 the description -- this is Sandra Wastler, sorry -- on
15 her handwritten page or the longer definition, I think
16 what the concern is is whether the ACMUI would find it
17 acceptable that someone that is an RSO but is not
18 listed on the license, can they sign attestations as
19 a preceptor even though they're not working as an RSO?

20 DR. HOWE: And they can provide the
21 supervised work experience to someone that's in
22 training to be an RSO.

23 MS. WASTLER: But they themselves are not
24 an RSO --

25 DR. HOWE: Are not.

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1 MS. WASTLER: -- on a license or working
2 in that capacity.

3 MEMBER LIETO: So what you're saying is
4 someone who meets the criteria of an RSO --

5 MS. WASTLER: Right.

6 MEMBER LIETO: -- has never been listed --

7 MS. WASTLER: Right.

8 MEMBER LIETO: -- can sign the attestation
9 for an RSO --

10 MS. WASTLER: Right.

11 MEMBER LIETO: -- by virtue of the fact
12 that --

13 DR. HOWE: By the definition of an RSO.

14 MS. WASTLER: Yes.

15 DR. HOWE: That's exactly what we're
16 saying.

17 MS. WASTLER: That's at -- that's the
18 interpretation of that part by OGC. And what we're
19 trying to find out is is that a problem? Is that
20 problematic?

21 MEMBER LIETO: I would think it would be
22 for your regions because they're going to have to now
23 look at the individual signing the attestation and
24 they're going to say they've never been as an RSO, now
25 you have to submit your credentials to me showing that

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1 you have the training and experience supervised by an
2 RSO. So somewhere down the line someone's going to
3 have to have been listed as an RSO that links all the
4 way back to this individual. And I can just see it
5 being an absolute nightmare.

6 DR. HOWE: And we understand that. That
7 is one of the effects. Because you aren't able to
8 check and see this person's an RSO.

9 Dr. Eggli?

10 MEMBER EGGLI: Could I ask a question
11 about actually 313A form for RSO? The one that I use
12 for authorized users for medical uses asks us in
13 addition to signing off as an authorized user
14 preceptor, it asks us to reference the relevant
15 material's license number. Does not the RSO form do
16 the same thing? Does it not ask you to reference the
17 relevant material's license number, which then gives
18 you a link back to a license where that RSO
19 theoretically is listed?

20 DR. HOWE: You are asked to provide a
21 license number. And you could still provide a license
22 number, but if you want back to that license number
23 where the person -- if the person is working at a
24 licensee's facility but they're not the RSO, they may
25 be a board certified health physicist, then you will

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1 not see their name as the RSO. As Ralph indicated,
2 the regions would then have to assure that that person
3 met the qualifications to be an RSO, is not listed as
4 an RSO but by definition in 35.2 was one.

5 MEMBER EGGLI: I think the problem may be
6 solved after -- or at least a recommendation might
7 come forth after Ralph's discussion about the
8 possibility of listing more than one RSO on a license.

9 DR. HOWE: And this person doesn't have to
10 work at a licensee's facility.

11 MEMBER EGGLI: Yes. But part of the
12 solution may be in the listing of multiple RSOs on a
13 license. Part of the problem is, again, the inability
14 to list more than one RSO on a license these days.

15 MS. WASTLER: Well, I don't think this is
16 necessarily tied to that. This is simply by
17 definition of being an RSO it allows somebody to
18 preceptor someone.

19 DR. HOWE: Yes.

20 MS. WASTLER: Whether they're listed on a
21 license or not. So it may not even be at that
22 facility.

23 MEMBER EGGLI: But they have to reference
24 a license number.

25 MS. WASTLER: They can provide a license

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1 number that they might be at the hospital that they're
2 at. But that doesn't mean that they're on it. They
3 don't have to be on it.

4 CHAIR MALMUD: Dr. Nag?

5 DR. HOWE: And they may provide an
6 explanation that they're not at a licensee facility.
7 We would have to go back to the definition and see if
8 that was in accordance with our regulations, and it
9 would be. So they wouldn't necessarily have to be at
10 a licensee's facility.

11 MEMBER NAG: I see a problem that if that
12 person has to be an RSO on a license, then
13 institutions that have many physicists who serve at
14 assisting RSO or they help the RSO and they provide
15 the training, now this person now, you know, at best
16 they're not on the license. So I don't think you need
17 to be on the license so long you know, you know, what
18 the requirements are to be an RSO.

19 DR. HOWE: Okay. And I think the thing
20 you have to also is really expand your thinking beyond
21 the person's working at a license facility. The
22 person just has to be board certified, have an
23 attestation and have training in any of the modalities
24 for which they're signing for.

25 MEMBER NAG: Right.

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1 DR. HOWE: They don't have to be at any
2 licensed facility.

3 MEMBER NAG: Right.

4 DR. HOWE: Okay.

5 MEMBER NAG: I mean, a coach doesn't have
6 to be the best football player.

7 DR. HOWE: Dr. Malmud?

8 CHAIR MALMUD: Has there been a problem?

9 DR. HOWE: I'm not sure how this came up
10 as a question, but it came in from one of our regions
11 and we looked into it. And we went, gee, this really
12 is kind of an issue.

13 CHAIR MALMUD: It's a theoretical issue?

14 MS. WASTLER: Yes.

15 CHAIR MALMUD: So right now it's --

16 MS. WASTLER: I would suggest, though,
17 that it probably -- the reason the region was asking
18 the question because it had come up in one of their
19 reviews. And because most of these issues that we're
20 talking about here have risen out of questions from
21 the regions, questions from other -- you know the
22 stakeholders. And so where we recognize that there's
23 some nuances here maybe that weren't intended. And I
24 believe this is one of them. So it may not have been
25 a big problem. It may have been on one particular

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1 case. But as a global matter, we would then look at
2 it to see what we needed to do and if it was
3 problematic in a larger scale.

4 CHAIR MALMUD: So if the individual is
5 board certified and is an authorized user currently,
6 that's sufficient? They need not be working as an RSO
7 in order to precept an RSO?

8 DR. HOWE: No. The definition of an RSO
9 in 35.2 says that you meet the qualifications in
10 35.50(a). Let me pull it up to make sure I'm speaking
11 correctly.

12 This is not 35.50. This is 35.2. To be
13 defined as a radiation safety officer you meet the
14 requirements in 35.50(a) or (c)(1), (a) and (c)(1) are
15 the board certification. (a) and (c)(1) also include
16 that you have an attestation. That you have completed
17 the training that was required for the board to be
18 recognized, and that you have sufficient knowledge to
19 function independently as an RSO.

20 Then the other requirements in 35.50 are
21 that you're identified as a radiation safety officer
22 on a license.

23 So it doesn't get to the second part of
24 it: You're identified as a radiation safety officer
25 on a license. That's already recognized. And that is

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1 similar to all of our other cases.

2 CHAIR MALMUD: Excuse me. It's still not
3 clear to me.

4 Currently, not in the proposal but
5 currently if the individual is boarded and has an
6 attestation, he or she need not be listed as the RSO
7 on a license in order to sign attestations as a
8 preceptor?

9 DR. HOWE: That's an OGC interpretation,
10 yes.

11 CHAIR MALMUD: That's the current?

12 DR. HOWE: Yes.

13 CHAIR MALMUD: And the question is should
14 it be changed so that in order to serve as a
15 preceptor, one should be boarded, have an attestation
16 and also work --

17 DR. HOWE: Function as an RSO.

18 CHAIR MALMUD: Yes, as an RSO. But each
19 institution only has one RSO. So this really limits
20 the pool significantly. And I don't know what
21 additional level of safety it offers to the public by
22 requiring that. Is there a practical increase in the
23 level of safety for the public and for users by doing
24 this?

25 DR. HOWE: I think the Commission has had

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1 a concept that it wants people that are actively
2 functioning in the field to be the individual
3 supervising the work experience and providing the
4 preceptor statements. This doesn't necessarily say
5 that they aren't functioning in the field. It just
6 says that they're not -- that they don't have to
7 function in the field.

8 MS. WASTLER: And I think the question
9 we're asking and based on some discussions I think
10 from yesterday, I think I heard the comment that in
11 radiation safety things haven't changed in many --
12 significantly in many, many years. So I think the
13 question we're raising is, you know, is this
14 interpretation that exists currently, is this
15 problematic in your mind. You know, does having an
16 RSO working in the field, does the actual being
17 functioning in that capacity during the time when they
18 attest to somebody, does it add significantly to the
19 process and increase health and safety?

20 CHAIR MALMUD: I understand the question.
21 And I understand what my answer would be. But I think
22 Dr. Williamson is chomping at the bit.

23 MEMBER WILLIAMSON: Yes. I would say no,
24 that making this more restrictive isn't going to
25 improve safety. And in fact the OGC interpretation

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1 may offer some modest relief to a severe shortage of
2 preceptor-able preceptors who can sign off on
3 radiation safety officers.

4 So, I would say leave it alone.

5 CHAIR MALMUD: Dr. Malmud concurs with Dr.
6 Williamson.

7 DR. HOWE: Yes, Sally?

8 MEMBER SCHWARZ: I'm just wondering if
9 there's a problem in terms of an RSO trying to sign
10 the attestation, you know that you're not able to
11 document who they are in terms of their ability to
12 sign this form? Maybe they can be submitting their
13 credentials as well.

14 DR. HOWE: Well, the net effect is if we
15 don't make any changes, then it becomes more of an
16 administrative problem where in the past if you gave
17 a name and you gave a license number, we go look at
18 the license number and we see the name. In this case
19 you give a name, they aren't listed on a license, so
20 then you have to provide that RSO qualifications when
21 you're providing your qualifications. And that could
22 go back several levels. Eventually you would have to
23 end up with, as Ralph indicates, someone listed on a
24 license to confirm.

25 CHAIR MALMUD: Debbie?

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1 MEMBER GILLEY: I believe it's how quick
2 you want to put this person on a license when it comes
3 to implementation. This is problematic for
4 implementation of getting people as RSOs on the
5 license. If we've got to go back and look at the
6 qualifications of the person who signed a preceptor
7 and they have to go back another level and look at the
8 qualifications who signed their preceptor, we could
9 get in this letters back and forth between the
10 regulatory community and the licensee.

11 DR. HOWE: And I think this is where the
12 issue of having one RSO on the license, being able to
13 list him on the license, might provide some --

14 CHAIR MALMUD: Some relief.

15 DR. HOWE: -- relief.

16 Jeff?

17 CHAIR MALMUD: Dr. Suleiman?

18 MEMBER SULEIMAN: I'm always conflicted.

19 All RSOs are not created equal. So what if
20 you've got an RSO in a very limited facility with very
21 limited responsibilities, board certified, whatever,
22 and attests to some other colleague who is about to
23 take responsibility for a much larger broader program,
24 that would work? I mean it's the quality of -- and
25 this qualification by reference sets up an

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1 administrative -- you know, a real difficult trail. It
2 just creates a lot of extra paperwork.

3 In the case that precipitated this
4 question, aside from not being able to track it
5 administratively, were the qualifications of the
6 people who were attesting, was that in question?

7 DR. HOWE: I think this one actually came
8 out of a different question. And in solving that
9 question, we came up with this one. So we were able
10 to solve our original one and then we realized we had
11 another.

12 There is a caveat here that says at least
13 when you get down to the training part the training
14 can either be provided -- may be satisfactorily
15 provided by being supervised by a radiation safety
16 officer, and then they list other people. And then at
17 the end it says, "Who is authorized for the types of
18 use for which the licensee is seeking approval?" So
19 the person that's not listed on a license wouldn't be
20 authorized for that. So the training part would come
21 in question, but when you get up to the preceptor
22 statement, you don't have that qualification. So you
23 can do the preceptor statement.

24 Ron? Can I get Ron?

25 DR. ZELAC: With respect to what you just

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1 said, Donna-Beth, we had a recent interpretation from
2 OGC that the training for the RSO can be given by
3 anybody. It doesn't have to be persons that are
4 restricted to the license. Anybody at all. It may be,
5 and that's why the word "may" is rather than "must."

6 DR. HOWE: And Ron is right. It is that
7 we did not specify exactly who had to give the
8 training, but if the training was given by a
9 supervising RSO, then that brings it down to here.
10 But you may not consider them a supervising RSO.

11 CHAIR MALMUD: To the public.

12 MR. WHITE: Gerald White, American
13 Association of Physicists in Medicine.

14 We're grateful that the NRC has recognized
15 the potential for increased documentation difficulty
16 in this case. But I should point out, first of all,
17 that this is yet another problem with the preceptor
18 concept for board certified individuals. Again, the
19 simple solution is to do away with the concept.

20 And secondly, I point out that the
21 documentation problem is not related to the particular
22 issue in question. The preceptor does not need to be
23 on a license at the time the preceptee applies for the
24 status. The preceptor needs to be on a license, have
25 been on the license at the time they signed the

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1 document. And that could as this rolls out in our
2 careers for 20 or 30 years, one would have to document
3 that the preceptor was on a license 10 or 20 or 30
4 years ago, which can be a very difficult process if
5 the regulatory community decides to require
6 documentation that the preceptor statement was
7 appropriately signed. It's going to require license
8 searches going back decades potentially.

9 DR. HOWE: Dr. Williamson?

10 MEMBER WILLIAMSON: Yes, I would say this
11 is not a problem for the regulated community, it's
12 only a problem for you if you insist on verifying the
13 accuracy or veracity of every preceptor's statement.
14 And I think, you know, a more reasonable approach
15 would be to assume, you know, that there is a prima
16 facie legal requirement that the person signed this
17 statement legitimately and honestly. And, you know,
18 if there were a random search of the credibility of
19 these preceptor statements and someone were caught
20 essentially perjuring themselves or fabricating a
21 preceptor statement, there would be a punishment.
22 Because I think that's how most legal documents work.
23 I think it seems irrational to insist on this burden
24 of proof for every transaction. I think you have to
25 believe somebody at some point.

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1 So if you wish to impose upon the public
2 this large cost that seems to add nothing to public
3 safety, well this is your problem, not ours.

4 DR. HOWE: From the public.

5 MR. BROGA: Yes. Dean Broga. I had one
6 comment and one question.

7 The question is I'm assuming you're not
8 eliminating the ability of a previously named licensed
9 RSO who has been named within the last seven years
10 from signing an attestation statement, like Dr.
11 Williamson who has been an RSO someplace --

12 DR. HOWE: No.

13 MR. BROGA: -- but isn't presently named,
14 but has been named in the last seven years; they're
15 still allowed to sign the attestation? That's not a
16 big problem for you to check that, right?

17 DR. HOWE: I don't think we are
18 eliminating anybody that meets the current
19 regulations. We're just saying this is something that
20 looks like it is larger than what we thought it was.

21 MR. BROGA: Well, but when you introduced
22 that you were saying "presently named." And so if I
23 was -- well, another RSO was named last year at my
24 facility, I wouldn't be presently named although I had
25 been named a year ago. And so I would assume the

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1 seven year time of experience and naming would apply.
2 But I can see where you could have an issue with this
3 if you allow this to go by this way where someone can
4 create an RSO academy outside his institution and
5 bring in people for training and not ever be on a
6 license. But I think a lot of this would be solved if
7 we had either the assistant or the alternate RSO
8 capacity to license so there were more people who
9 could be on a license who would be credible and easily
10 looked up by the NRC.

11 So, I hope Ralph's going toward something
12 along that line.

13 CHAIR MALMUD: All right. Ralph.

14 MEMBER LIETO: Go ahead.

15 CHAIR MALMUD: I was just going to try and
16 summarize this by saying it seems to me, Donna-Beth,
17 that the feeling of the majority of the members of the
18 Committee is that we should leave it as it is and not
19 recommend the change. There are other elements that
20 will be addressed later, but he probably will bring
21 up, that we may feel need changing. But it seems the
22 majority does not feel this needs changing. Is that
23 the spirit of the Committee?

24 The answer is apparently unanimously yes.

25 DR. HOWE: Okay.

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1 MEMBER NAG: Do we want to record it as a
2 vote that we --

3 CHAIR MALMUD: You wish to make a motion?
4 We will do that.

5 MEMBER NAG: Yes. I make a motion that
6 the present definition of RSO preceptor not be
7 changed.

8 CHAIR MALMUD: A second to the motion that
9 it not be changed? Dr. Schwarz.

10 All in favor? Any opposed. Any
11 abstentions? It's unanimous.

12 DR. HOWE: Okay. Thank you.

13 The second issue is 35.12. In 35.12, this
14 is more of an issue on covering all our bases for
15 determining burden for OMB.

16 Our individuals down in our OMB review
17 group looked at our language in 35.12 and said that
18 because we don't have "or equivalent" in the
19 regulations, that even though our practice is to
20 include any type of amendment or any type of renewal,
21 or any type of new license as a burden attached to the
22 313 form, and the 313A is a part of the 313 form, that
23 we associate any burden that's associated with
24 information an applicant has to provide on training
25 and experience to the 313 form. And the folks down

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1 that are reviewing our OMB clearance said, "Well, you
2 really need to say that these letters that could also
3 be used," because a new application you do have to do
4 a 313. The 313A has always been voluntary, but you
5 have to provide the information in the regulation, and
6 that's where the burden is coming from. It's not
7 coming from the form, it's coming from the regulation.

8 That you don't have that these letters
9 have to have equivalent information, and therefore
10 technically the burden for the letters is not included
11 in the 313. And so this is more or less a -- and then
12 you see our rulemaking -- our potential would be to
13 revise 35.12 to add "or equivalent" so it's clear that
14 anytime you supply the information required by the
15 regulation, that burden can be attached to the NRC
16 forms.

17 CHAIR MALMUD: Does someone wish to make
18 a motion that the letter should be "or equivalent?"

19 MEMBER LIETO: So moved.

20 CHAIR MALMUD: Is there a second to the
21 motion?

22 MEMBER EGGLI: Second.

23 CHAIR MALMUD: It's been moved and
24 seconded.

25 Any discussion that the letter should have

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1 "or equivalent" information which is currently in form
2 313?

3 All in favor?

4 (Vote by show of hands).

5 CHAIR MALMUD: You got it.

6 Next.

7 DR. HOWE: Okay. Now we're into
8 35.50(c)(2), which is an area that is familiar to
9 everyone.

10 As written the AU, AMP and ANP has to be
11 listed on the licensee's license. While that makes
12 some amount of sense, in other words if the person is
13 listed on the license and they're familiar with your
14 program, and therefore they should be able to step in
15 quickly to be an RSO for similar types of uses, it is
16 to some extent restrictive because you could have an
17 individual that is an AU, AMP or ANP on another
18 license and that individual would be qualified to be
19 -- we believe would be qualified to be an RSO for the
20 similar types of uses. And so the problem is that we
21 think the language listed on the licensee's license
22 may be too restrictive. And so we're looking at
23 making a change that might be similar to this listed
24 on a license or NRC master materials permit that
25 authorizes similar types of use of byproduct material

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1 and the individual has experience in radiation safety.
2 So we're looking to kind of expand that with just the
3 licensee's license to any license having similar uses.

4 CHAIR MALMUD: Any discussion.

5 MEMBER NAG: I would support that move.

6 CHAIR MALMUD: Dr. Nag makes a motion to
7 accept the change. Is there a second to the motion?

8 MEMBER EGGLI: Second.

9 CHAIR MALMUD: Any discussion?

10 All in favor? I need a vote. Did I hear
11 something?

12 MEMBER LIETO: Well, I have a question.
13 I'm trying to be sure that you're saying that for some
14 reason it sounds like it's going to make it more
15 restrictive.

16 DR. HOWE: The way the regulation --

17 MEMBER LIETO: I don't know, from what you
18 just said earlier I don't think that was your intent.

19 DR. HOWE: No. The way it is written now
20 you have the same verbiage. And when you get to
21 identify, the identified is on the licensee's license.
22 This would expand it to a license or master materials
23 license permit. And the license in this case would be
24 an NRC license or an agreement state license.

25 I don't have all the words here. And when

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1 we get into rulemaking space, if we get into
2 rulemaking space, then that will be flushed out to say
3 an NRC or an agreement state license for the
4 authorized user, authorized medical physicist, or
5 authorized nuclear pharmacist would also be a permit
6 issued by an NRC or an agreement state broad scope
7 license or a master materials licensee broad scope
8 permittee. So you would have a lot more verbiage in
9 here, but this is just to give the concept.

10 CHAIR MALMUD: Any other questions?

11 All in favor?

12 (Vote by show of hands.)

13 CHAIR MALMUD: Any opposed? Any
14 abstentions?

15 DR. HOWE: Ralph is abstaining.

16 CHAIR MALMUD: One abstention, otherwise
17 all in favor.

18 DR. HOWE: Okay. Now this is a
19 continuation of the problem in 35.50, and that is that
20 the preceptor RSO is required to provide an
21 attestation, and this is for already identified AUs,
22 AMPs and ANPs that are qualified under 35.50(c)(2) to
23 be RSOs. We find the RSOs are reluctant to sign the
24 attestation.

25 We also went back and looked at the

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1 original intent of the rulemaking in 2002 and in 2005.
2 And from the statements of consideration it appeared
3 as if the original intent was not to have an
4 additional preceptor attestation. So what we are
5 recommending in this case is to take out the preceptor
6 attestation for the already recognized AUs, AMPs and
7 ANPs. And this is just kind of a potential way of
8 addressing that, and that would say that no
9 attestation is required for those individuals meeting
10 the requirements of (c)(2), the "or" doesn't belong
11 there if they have RSO responsibilities for similar
12 types of use for which the individual is authorized.

13 CHAIR MALMUD: Is there a motion to
14 approve this?

15 MEMBER VAN DECKER: May I just ask a
16 question?

17 CHAIR MALMUD: Okay.

18 MEMBER VAN DECKER: That one --

19 CHAIR MALMUD: Beg your pardon?

20 DR. HOWE: Yes.

21 CHAIR MALMUD: Go ahead.

22 MEMBER VAN DECKER: And I'm sorry for
23 interrupting.

24 So in simple North Jersey language,
25 because I get confused easily in life, this would mean

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1 that essentially we would be back to kind of the old
2 35 where an authorized user with skills in the
3 modality in which they were trained could serve as an
4 RSO on a small license for that modality; is that
5 where this kind of leads us to?

6 DR. HOWE: That's exactly right.

7 MEMBER VAN DECKER: Not bad for North
8 Jersey. Okay. Thank you.

9 DR. HOWE: Orhan?

10 CHAIR MALMUD: Any other questions?

11 MEMBER SULEIMAN: I have a question the
12 way it's worded. In other words, I get the impression
13 that forget the attestation issue which is an issue
14 all by itself, but if in this case they will not
15 attest because they don't consider that person
16 qualified for what they're going to do and may
17 withhold that?

18 DR. HOWE: The issue is you have to have
19 an RSO. And if the licensee is a small licensee and
20 they lose their RSO, then they don't have a person
21 that knows them, so you have to go outside of that
22 facility to another facility. And what we're hearing
23 at the ACOM meetings is when you go outside of that
24 facility, the RSO on another license doesn't know the
25 individual and is not willing to sign.

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1 MEMBER SULEIMAN: So it's an unnecessary
2 paper exercise? Okay. Okay.

3 DR. HOWE: And we looked back at the
4 intent of what we have really wanted to do in 2002 and
5 2005. And because we restructured this 35.50 at the
6 last minute, this type of person --

7 MS. WASTLER: It was amended.

8 DR. HOWE: -- came up above the
9 attestation where before they came below the
10 attestation, it was clear that they didn't require it.

11 MEMBER SULEIMAN: So the failure to attest
12 in this case is strictly that they don't know the
13 individual, rather than they know them and they don't
14 think they're competent?

15 DR. HOWE: Yes.

16 Dr. Nag?

17 MEMBER NAG: The thing is the admission go
18 along with the ACMUI suggestion that the preceptor
19 statement was saying but that we eliminate it, then
20 this is something that doesn't require further
21 confirmation. Because, you know, we are asking the
22 permission that the entire preceptor statement should
23 be adequate for everyone. So then this rule doesn't
24 even need to be there because there will be no need
25 for perceptorship for anybody, including RSO and then

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1 authorized users. So --

2 CHAIR MALMUD: But currently --

3 MEMBER NAG: Right.

4 CHAIR MALMUD: -- it would be a useful
5 addition?

6 MEMBER NAG: Right.

7 DR. ZELAC: Point of clarification.

8 CHAIR MALMUD: Dr. Zelac?

9 DR. ZELAC: This is Dr. Zelac.

10 I thought that the approach that the
11 Advisory Committee was taking was to recommend to the
12 Commission that attestations not be required for board
13 certified -- people seeking authorized status via the
14 board certification pathway. What I just heard from
15 Dr. Nag was get rid of all preceptor statements
16 period, which would include the alternate pathway. I
17 didn't think that that was the intent?

18 MEMBER NAG: Oh, right. The board
19 certification, those who are board certified. I meant
20 for those who are board certified.

21 DR. ZELAC: Okay. Fine. Thank you.

22 DR. HOWE: And this is not limited to
23 those that are board certified. This is anybody
24 that's identified as an authorized user, nuclear
25 pharmacist or a medical physicist.

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1 CHAIR MALMUD: Is there a motion to
2 support the change?

3 MEMBER SULEIMAN: So moved.

4 CHAIR MALMUD: And seconded.

5 All in favor.

6 (Vote by show of hands.)

7 CHAIR MALMUD: Any abstentions? Any
8 negative?

9 Unanimous again.

10 DR. HOWE: Okay. And this is the
11 experienced radiation safety officer. This is
12 35.57(a). And 35.57(a) deals with experienced
13 radiation safety officers, teletherapy or medical
14 physicists or nuclear pharmacists.

15 And as written this particular part of the
16 regulation specifically states the individuals need
17 not comply with the training requirements of 35.50,
18 .51, or .55 respectively. The effect of that is that
19 we may have RSOs and AMPs that are either currently at
20 a licensee's facility that gets a new modality, and in
21 this case we're not talking about a new device in an
22 existing authorization for the license, but maybe goes
23 into gamma knife or goes into HDR, or going into tele
24 -- probably not teletherapy. Or they go into manual
25 brachytherapy when they used to be nuclear medicine.

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1 So they're going into some new modality. And the way
2 the experience one reads that person does not need
3 additional training in that new modality to function.
4 So if you're already listed on a license as an AMP or
5 an RSO, you wouldn't need the additional training.
6 And so what we're looking for is a similar statement
7 to what we have for authorized users. And that is
8 that these experienced individuals would be recognized
9 as experienced individuals when using or responsible
10 for the same materials and uses that they were already
11 recognized for. And that would bring in the education
12 requirement if a new modality was added.

13 CHAIR MALMUD: Dr. Nag?

14 MEMBER NAG: Yes. Leave it the way it is,
15 but I would suggest why not expand it to experience
16 authorized user as well? Because authorized user, if
17 you have been using that for several years at your
18 institution and you move to another institution,
19 wouldn't they face the same problem?

20 DR. HOWE: Dr. Nag, this would be making
21 a conforming change to what is already required for
22 the authorized user. The authorized user statement in
23 35.57(b) states that the authorized user will be
24 recognized as an authorized user for the same
25 materials that he had, was listed for before.

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1 Jeff?

2 MEMBER WILLIAMSON: Yes. I'm concerned
3 about this change because I think the intent of the
4 grandfathering clause was to in fact exempt a group of
5 previously practicing medical physicists or RSOs and
6 so forth who were basically compliant with the older
7 requirements from having to meet the new requirements
8 so that they would be in a position to sign preceptor
9 statements for physicists and pharmacists and so forth
10 emerging under the new set of rules.

11 So I would, based on this, oppose the
12 proposal.

13 DR. HOWE: Ralph?

14 CHAIR MALMUD: Mr. Lieto?

15 MEMBER LIETO: Yes. I think this would
16 actually make it more restrictive on previously
17 identified RSOs. And I would move that the Committee
18 not support this change.

19 MEMBER NAG: Will someone clarify again
20 why would that make it more or less -- let's say you
21 were grandfathered for HDR and so on, and then now you
22 have a new modality like gamma knife that you have no
23 training for, you would not have previously been
24 allowed to have done gamma knife. And now all of a
25 sudden you can use gamma knife? I'm not sure. Maybe

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1 I'm not getting something.

2 MEMBER WILLIAMSON: I'm not sure you were
3 previously. The only designation that existed was
4 teletherapy physicist. And so that is the only basis
5 at that time for a physicist to have been in the
6 license, so it's necessary for that certification to
7 accommodate HDR --

8 DR. HOWE: Jeff, that's not right.

9 MEMBER WILLIAMSON: -- and other
10 modalities.

11 DR. HOWE: That's not quite true. When
12 the HDRs and the gamma knives came in, NRC started
13 right at the beginning listing those medical
14 physicists and those authorized users for the HDR and
15 the gamma knife use specifically. So we listed more
16 than just teletherapy physicists.

17 We didn't call them authorized medical
18 physicists, but we did list them for those uses. So
19 in 2002 we had a long history of having many kinds of
20 physicists listed with 600 uses.

21 The public?

22 MR. BROGA: Could I just ask for some
23 clarification on this and the last question?

24 Although you're doing away with
25 attestation, I would assume you're not doing away with

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1 the form that the individual has to submit requesting
2 to be named RSO and to clarify that at least they
3 state that they're aware of the regulations that are
4 in that present form? And the same would be true here
5 if you made this requirement, it would be free of
6 attestation but the individual would have to submit a
7 form requesting it at the time they changed the
8 license?

9 DR. HOWE: I'd like to go back. When
10 you're talking about the RSO, are you referring back
11 to an earlier discussion?

12 MR. BROGA: The previous discussion you
13 did away with attestation, but I would assume that the
14 person is still going to have to send a request to be
15 named, and I would assume you would be using a similar
16 form to the 313, it just wouldn't have to be attested
17 to? The individual would have to state they had the
18 things, but there would be no attestation?

19 DR. HOWE: Our forms today conform to the
20 current regulations. If we change the regulations and
21 that affects the information that is provided, we will
22 make corresponding changes to the forms.

23 Right here right now I can't tell you if
24 there would be a change and what that change would be.
25 But I will tell you that if we make regulatory

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1 changes, we will bring the forms into conformance with
2 those regulatory changes. So if we no longer require
3 an attestation for something, we'll make it clear on
4 the form there is no longer an attestation for that.

5 MR. BROGA: But if you made this change
6 right here, unless you took away the attestation, this
7 would require attestation, too; am I not right?

8 DR. HOWE: If you will wait a minute,
9 you'll see that I have another slide on 35.57(a) that
10 says that if you were to accept this, the Staff's
11 intent is that if the person needs additional training
12 to be an RSO for a new modality or an AMP for a new
13 modality, that we were specifically recommending that
14 the attestation not be required.

15 MR. BROGA: Thank you.

16 CHAIR MALMUD: Any other questions for
17 discussion?

18 Is there a motion on the floor? Will
19 someone make a motion?

20 MEMBER LIETO: I would move to not support
21 this addition because I think it would make it more
22 restrictive.

23 MEMBER WILLIAMSON: Second.

24 DR. HOWE: May I put in? So, Ralph, if I
25 have an RSO that is an RSO in a nuclear medicine

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1 facility, then without additional training that person
2 can be an RSO with a gamma knife and an HDR?

3 MEMBER LIETO: Well, that's not --

4 DR. HOWE: That's what the regulation says
5 right now.

6 MEMBER LIETO: Well, that's not the way I
7 would interpret what you have there. Okay. If
8 somebody says -- say if somebody was an RSO for 100,
9 or say 100 through 300, okay. And somebody goes
10 someplace else and they want 100, 300 and 1,000; they
11 couldn't do it.

12 DR. HOWE: It would depend on what the
13 1,000 is. If the 1,000 is similar to 100, 200 and
14 300, then it's no.

15 MEMBER LIETO: To me what you're doing,
16 though, is you're making it more restrictive. It
17 creates a paperwork burden for everybody involved.
18 And I don't see what the added health and safety
19 issues are here. Because it states that when you go
20 to apply for an RSO, you still have to demonstrate
21 that you have training and experience in the uses that
22 you're applying for.

23 If someone says they have training and
24 experience for that purpose --

25 DR. HOWE: What we're saying is that this

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1 particular regulation as written says you as you're
2 applying for an RSO to a new position with
3 significantly different modalities do not have to
4 provide documentation of your training and experience
5 to handle the radiation safety for those significantly
6 different modalities. Because you are grandfathered
7 here and are exempted from the requirements of meeting
8 anything in 35.50.

9 MEMBER WILLIAMSON: Well, I believe that's
10 legitimate. That's the definition of grandfathering.
11 I agree with that. That's how it used to be under S
12 Subpart J, and it was not a problem. So the fact that
13 one does not require documentation of this additional
14 training, does not mean that a competent and
15 professional individual would not seek out whatever
16 training they would need. So I believe that other
17 mechanisms within the community to ensure appropriate
18 credentialing would prevail. And given the risk of
19 liability of having a major accident because of an
20 incompetent or poorly trained RSO, I think that
21 hospitals and licensees would be responsible in
22 ensuring that adequately credentialed people were
23 staffing this very important function.

24 So, again, I would urge the Committee to
25 support Ralph's motion.

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1 DR. HOWE: Dr. Malmud?

2 CHAIR MALMUD: I have a question. If there
3 is a medical physicist who is the physicist for a
4 nuclear medicine division in a large university
5 hospital and he or she chooses to become the physicist
6 for a teletherapy unit freestanding, not part of a
7 hospital which has a credentialing committee, but a
8 freestanding, currently that physicist can jump from
9 nuclear medicine to radiotherapy in a freestanding
10 therapy unit with no experience in radiotherapy?

11 MEMBER WILLIAMSON: That's not true.

12 DR. HOWE: No.

13 MEMBER WILLIAMSON: No. Because there is
14 never --

15 CHAIR MALMUD: I'm asking a question. I'm
16 trying to get the answer.

17 DR. HOWE: In that particular case when
18 they're moving from a medical physicist in one
19 position to be a medical physicist in another
20 position, it's not true. Because we do not recognize
21 and authorize medical physicists in diagnostic nuclear
22 medicine. So that individual would not be an
23 authorized medical physicist and would have to meet
24 the criteria for an authorized medical physicist,
25 which are the uses in 35.600.

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1 If that medical physicist wanted to be the
2 RSO, then they would not have to demonstrate that they
3 had training in radiation safety, regulatory issues or
4 emergency procedures for the new responsibilities of
5 handling the 600 uses.

6 CHAIR MALMUD: So currently a medical
7 physicist with no experience in teletherapy could go
8 from a radiology department in a university hospital?

9 MEMBER WILLIAMSON: No.

10 CHAIR MALMUD: No? That's what I'm trying
11 to understand.

12 DR. HOWE: Well, if he's a medical
13 physicist -- you have to keep two terms in mind. Is he
14 a medical physicist? Okay. NRC does not regulate or
15 recognize all medical physicists. We only identify
16 those medical physicists that work on teletherapy
17 units, HDRs, gamma knives and eye applicators as
18 authorized medical physicists.

19 CHAIR MALMUD: Thank you. That clarifies
20 my question.

21 DR. HOWE: They still --

22 CHAIR MALMUD: Okay. I understand.

23 DR. HOWE: Dr. Welsh?

24 MEMBER WELSH: As I understand it, the
25 problem is that as written right now if an institution

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1 adds a new modality like purchasing a gamma knife,
2 there is no requirement for documentational proof that
3 anybody has experience or preparation that would allow
4 them to use this equipment safely?

5 DR. HOWE: That is correct.

6 MEMBER WELSH: And that would appear to be
7 a potential problem? The authorized user, medical
8 physicist and the RSO might appropriately be required
9 to get some vendor training, perhaps, to document that
10 this institution and these individuals can now use
11 this equipment at this institution responsibly and
12 safely. Is that the spirit of what you're proposing
13 here?

14 DR. HOWE: That is the spirit. The
15 authorized user is already covered because they are
16 only authorized for those uses that they have
17 experience with. And so the authorized user would
18 have to get additional training in the gamma knife.
19 But the medical physicist would not, and the radiation
20 safety officer would not.

21 MEMBER WELSH: So it would seem that it's
22 logical that we would all favor getting that
23 additional training experience and documentation that
24 is appropriate for illustrating that this equipment
25 can be handled competently and safely at the

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1 institution. But it might be the verbiage that we're
2 not in agreement with here?

3 MEMBER WILLIAMSON: No, it's not. I'm in
4 disagreement with the concept of trying to restrict
5 the definition of grandfathering. This applies only
6 to a very limited segment of medical physicist, the
7 practitioners; those that meet the recency of training
8 requirement plus were mentioned on a license prior to
9 2002.

10 CHAIR MALMUD: Dr. Nag?

11 MEMBER WILLIAMSON: As an authorized --

12 MEMBER NAG: Donna-Beth, would you tell us
13 what would be needed for somebody who is a radiation
14 safety officer currently at that institution and now
15 moves to a new institution and is now asked to take
16 charge of any of the modality in addition to what you
17 were trained for? So for example, he never had any
18 training on gamma knife and was an RSO, but then went
19 to a new place that had in addition gamma knife.
20 Would he only require some training for the gamma
21 knife or would it be that well he has to do everything
22 all over again? I think that is the distinction I
23 would like to know.

24 DR. HOWE: In this particular section on
25 the regulation if he was listed as an RSO on a license

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1 with no gamma knife prior to -- and you can go down to
2 the October 2005, and he goes to this new facility
3 that has the gamma knife, we would not be able to
4 require him to have training in the gamma knife. If
5 we could require him to have training, the training
6 would be the training that's specified in paragraph --
7 I think it's (e) maybe (d), for the RSO, which is that
8 they would have training in the radiation safety, the
9 regulatory issues and the emergency procedures for the
10 gamma knife. We would not require him to start all
11 over again as a radiation safety officer. We would
12 just require those modality-specific training
13 elements.

14 Dr. Eggli?

15 MEMBER EGGLI: Is there any in this
16 retraining or additional training? Who sets the
17 threshold for what represents sufficient training? Is
18 that a case-by-case basis? There is some potential
19 for inconsistency in determination of what's adequate
20 training. Does the individual site determine what's
21 adequate training? Does NRC Regions individually
22 interpret what's adequate training?

23 DR. HOWE: We don't prescriptively say
24 what the training, how you have to get the training.
25 We do indicate that we would assume that it is

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1 acceptable if the training was provided by: In the
2 case of the RSO, it could be an RSO with experience in
3 that modality, an authorized user with experience in
4 that modality, an authorized nuclear pharmacist with
5 experience in that modality, or an authorized medical
6 physicist with experience in that modality.

7 MEMBER EGGLI: The problem is it may be --

8 DR. HOWE: So it would be somebody
9 authorized with the modality.

10 MEMBER EGGLI: Okay. It may be hard to
11 come across that kind of training. Most of the
12 training delivered for new modalities in reality is
13 delivered by the vendors. And that's how most of this
14 sort of new modality training gets delivered in
15 finding someone that actually -- where you can go away
16 to a site that has a volume adequate to be trained by
17 an authorized individual of some class, is potentially
18 problematic.

19 DR. HOWE: Well, Dr. Eggli, I want to
20 clarify that we don't specify where you get the
21 training. We say you may get it. That does not
22 preclude you from getting it from a vendor. And we
23 like it when you get vendor training because we feel
24 you're getting it from the horse's mouth.

25 So we are not excluding vendor training at

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1 all.

2 I think the way it was written was the
3 idea that we're not talking just about new modalities
4 where the vendor training is probably the best. We
5 may be talking about an RSO going into a facility that
6 already has experienced people there, and then he
7 needs additional training on what he sees there.

8 MEMBER EGGLI: Thank you.

9 CHAIR MALMUD: We have a member of the
10 public.

11 MR. WHITE: Yes. Gerald White, AAPM.

12 I'm trying to understand this discussion
13 with the one that's to follow, because I think they're
14 inextricably linked.

15 But it seems to me that we have already
16 eliminated everyone board -- with the exception of the
17 50 or health physicists people, we've eliminated
18 everyone board certified prior to now from using the
19 board certification pathway for this. And now we're
20 eliminating any experienced RSO who didn't have
21 experience with the particular modality in the new
22 institution prior to October of '02.

23 For example if one did not have a gamma
24 knife in 2002 but had one in 2005 and wanted to go to
25 an institution that had a gamma knife, would they be

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1 excluded then from using the experienced pathway to --

2 DR. HOWE: No. No. The intent, and let
3 me go to the next slide, would be if we make this the
4 revision ahead. Our intent is not to require
5 attestation, but just to require the completion of the
6 training that would be required in 35.50(e), that
7 would be say for the RSO. And if it was the
8 authorized medical physicist, it would be the training
9 that's in 35.51. And it's always specific to whatever
10 this new use is.

11 It's the radiation safety, it's the
12 regulatory issues, it's the emergency procedures for
13 that new use that that person didn't have
14 responsibility for earlier. So we would be saying we
15 would expect an experienced authorized user or medical
16 physicist -- because the nuclear pharmacist really
17 doesn't have any other area than nuclear pharmacy.
18 And so when they go from place-to-place-to-place
19 they're doing their same thing. So it's the medical
20 physicist and the RSO.

21 If you do not have responsibility for
22 those things, we're saying you need the additional
23 training. And we're saying because you're an
24 experienced individual, we would not require you to
25 have an attestation, but that you would have completed

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1 this additional training. So that you know the
2 radiation safety, the regulatory issues and the
3 emergency procedures associated with this modality
4 that you didn't have experience with before. That's
5 all we're saying.

6 CHAIR MALMUD: Mr. Lieto?

7 MEMBER LIETO: Dr. Malmud, two points.
8 One we've made a motion and I think maybe we need to
9 vote on that motion.

10 But in terms of background, we didn't see
11 this until we walked in. And it seems like we're
12 getting into a debate on revising the rules on
13 information none of us had seen before we walked in
14 here. And I think, you know, it's one thing if some
15 things are like really, you know, black and white
16 changes like the equivalency request and so forth.
17 But, obviously, we're not convinced by this change.
18 There's not any support on the Committee on this. And
19 we're getting into debates on trying to convince being
20 convinced that we want to make this change.

21 I think if there's some health and safety
22 issue that's really urgent that needs resolution at
23 this meeting, I think Staff needs to come back to us
24 to prove what health and safety issue is being
25 resolved or being solved by this issue, by changing

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1 this rule.

2 And also I think it would -- I think with
3 all these proposed rule changes, or I should say not
4 proposed rule changes, but suggested rule changes, I
5 think it would have been nice to have this at least
6 maybe a day beforehand to digest to see if there are
7 some other issues. What we're basically doing is
8 flying on the cuff.

9 And so back to my original point. If we
10 need to make a motion on this before we can move
11 forward --

12 CHAIR MALMUD: You did make a motion.

13 MEMBER WILLIAMSON: You made a motion and
14 it was seconded.

15 MEMBER LIETO: And I would like to move
16 forward.

17 CHAIR MALMUD: You made a motion, it was
18 seconded and we're discussing the issue. And I don't
19 believe that we have heard as yet the feelings of the
20 whole Committee. But we certainly know your position
21 and Dr. Williamson's position.

22 If you would prefer rather than moving on
23 your motion, to have this issue tabled for a later
24 date, this one specific issue, we can do that.

25 MEMBER LIETO: That would be fine.

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1 MS. WASTLER: I would propose --

2 MEMBER LIETO: Well, no. I was --

3 MS. WASTLER: First of all, I'd like to
4 apologize. You know, sometimes we do our best to try
5 to get this information out to everyone ahead of time.
6 But as you are all aware that, you know, that
7 sometimes isn't possible. And in this case was one of
8 them. You didn't get it until this morning.

9 So unless there is something burning done
10 about that I'm not aware of, I have no objection if
11 the Committee would like to table the rest of the
12 discussion so that they could look at the information
13 and we can bring it up in another venue at another
14 time.

15 You know, I understand that it's
16 difficult. Part 35 is difficult. And basically you
17 need the time to review it, and I understand that.

18 So I would like to put that on the table
19 as well.

20 CHAIR MALMUD: Getting back to your
21 motion, would you rather have your motion on this item
22 tabled? In other words, table this item?

23 MEMBER LIETO: On this specific --

24 CHAIR MALMUD: This specific item?

25 MEMBER LIETO: I'll leave this one on the

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1 table since I'm not going to change my mind later on.
2 So I'm changing the grandfathering. So I'd like to
3 keep this issue on the table with the motion seconded
4 by Dr. Williamson.

5 CHAIR MALMUD: All right. So we have the
6 motion moved and seconded. We've had some discussion.
7 Is there any further discussion of this particular
8 item? Any -- yes, Dr. Welsh?

9 MEMBER WELSH: From my interpretation of
10 what I've read and what I've heard during the
11 discussion, I'm strongly in favor of it. Because it's
12 coming to us at such short notice and there's
13 obviously dissension, I would favor tabling this and
14 allowing us to digest it, to think about it more
15 carefully, read exactly what it says and resume
16 discussion at a later time.

17 CHAIR MALMUD: Thank you.

18 Dr. Schwarz?

19 MEMBER SCHWARZ: I agree with that. I
20 think it would be helpful for those of us who --

21 MEMBER NAG: And I think a vote on this
22 issue is limited here. We need more discussion. And
23 I'm in favor of tabling it.

24 CHAIR MALMUD: The motion to table
25 supersedes the original.

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1 Is there a motion to table?

2 MEMBER NAG: Second.

3 CHAIR MALMUD: Dr. Welsh, Dr. Nag seconds
4 the motion to table.

5 Any discussion of the motion to table, if
6 not all in favor of the motion to table this issue,
7 this one item?

8 (Vote by a show of hands.)

9 CHAIR MALMUD: Opposed to tabling the
10 item? Three opposed.

11 PARTICIPANT: Four opposed.

12 CHAIR MALMUD: How many? Four? Five?
13 Who's for tabling it? One, two, three, four, five.
14 And opposed? One, two, three, four.

15 So the motion is tabled.

16 MEMBER NAG: The closest vote we've ever
17 had.

18 CHAIR MALMUD: Yes, it is. It is.
19 However, it does fulfill the spirit of your concern,
20 which is that we should not move on it today. So I
21 hope that you recognize it. It is a partial victory.

22 MEMBER LIETO: You recognize I won't
23 change my mind.

24 CHAIR MALMUD: All right. Dr. Howe, can
25 we move on to the next item?

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1 DR. HOWE: The next one is 35.75, and you
2 may also want to table this one because it may involve
3 quite a bit of discussion.

4 As written 35.75 says that patients can be
5 released if they're not likely to exceed five
6 millisieverts or .5 rem. There is no addition in here
7 as to the time frame that this can be given in. If we
8 go back to our statements of consideration and review
9 of when this rule was put into effect, it is clear
10 that the Commission did not want to require people to
11 keep records, but it is not clear that the Commission
12 didn't believe that the radioactive material given or
13 the radiation treatment given was for any more than
14 one year. And so the Staff in going back now sees
15 that our rulemaking language was not in keeping with
16 the intent and is recommending changing it to 5
17 millisieverts per year.

18 CHAIR MALMUD: Dr. Eggli?

19 DR. HOWE: Dr. Eggli?

20 MEMBER EGGLI: Probably this affects me
21 more than anybody else because you're probably dealing
22 with nuclear medicine type therapeutic procedures.

23 If I'm going to approach a five
24 millisievert per year exposure to a family member,
25 which is really what we're probably talking to because

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1 the general public is very unlikely. So anybody who
2 lives in close proximity. I'm going to be at the
3 higher end of the dose range.

4 The calculations come out around 180 to
5 185 millicuries is what it takes to produce that 5
6 millisievert dose. The likelihood that I would repeat
7 that in one year because of questions of bone marrow
8 suppression is very unlikely.

9 So I actually don't have a problem with
10 this.

11 DR. HOWE: Okay.

12 MEMBER EGGLI: Because I don't think it's
13 going to impact my practice.

14 CHAIR MALMUD: Could you clarify it for
15 us, Dr. Eggli, when you say you don't have a problem
16 with it, you don't have a problem with changing it or
17 with leaving it the way it is?

18 MEMBER EGGLI: I do not have a problem
19 adding the per year stipulation.

20 CHAIR MALMUD: Thank you.

21 MEMBER EGGLI: That will not change my
22 clinical practice.

23 MEMBER NAG: From a radiation oncologist
24 perspective, it's not going to change. And in fact,
25 having it per year may be helpful, because otherwise

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1 someone may say that 5 millisieverts refers to the
2 entire life span, which means that you can't repeat.
3 So I would be in favor of per year.

4 CHAIR MALMUD: You're in favor of per
5 year?

6 MEMBER WILLIAMSON: Yes, I like it.

7 CHAIR MALMUD: Any other --

8 DR. HOWE: Wait a minute. We have a
9 public --

10 CHAIR MALMUD: Dr. Williamson, I think
11 you're next.

12 MEMBER WILLIAMSON: Yes. Donna-Beth, has
13 there been a particular case or incident that
14 motivated consideration of this change?

15 DR. HOWE: Yes, there has. There was a
16 case in which three different administrations were
17 intended to be given that in the end would take the
18 family member over this limit.

19 CHAIR MALMUD: I think Dr. Suleiman, then
20 a member of the public.

21 MEMBER SULEIMAN: Is the five
22 millisieverts, that's a general public? Did we ever
23 come up with a caregiver limit? I know we debated
24 this quite a bit about a year or so ago. I mean, I'm
25 all for considering family members or caregivers in a

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1 slightly different category. But I would be concerned
2 that this say any individual. I think if the family
3 could keep track of their individuals, this could
4 easily be managed around. But I think there's a real
5 concern with multi-modality imaging and other
6 technologies and people being given care in different
7 facilities that we're seeing people getting multiple
8 examinations and sometimes they're therapeutic at
9 different places. So that potential exists. I don't
10 know if it's completely relevant here, but --

11 DR. HOWE: This particular regulation is
12 not restricted to family members. It is written in
13 very broad terms. It is any individual that is likely
14 to exceed level. And then there's --

15 MEMBER EGGLI: The one year wouldn't hurt.
16 It would just require a little bit more attention to
17 managing the patient and whom those people are going
18 to be exposed to, which I think should be good
19 practice in the first place.

20 CHAIR MALMUD: Members of the public?

21 PARTICIPANT: I concur with Dr. Howe.

22 CHAIR MALMUD:

23 Please introduce yourself?

24 MR. BROGA: Dr. Broga, DCU.

25 I concur. This does happen, and it also

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1 if it's going to stand like this, I don't know what
2 we're defining as a year, a calendar year before the
3 date of the therapy or 12 months of the date of
4 therapy. Because we do have individuals who are
5 getting multiple therapy in a 12 month period of time.
6 And it would employ those applying the therapy to
7 ensure that it has not occurred in the previous 12
8 months. So there would be a necessity for people to
9 ask patients have you received the treatment in the
10 previous 12 months before we released under these
11 criteria.

12 CHAIR MALMUD: Thank you.

13 DR. HOWE: Dr. Eggli?

14 MEMBER EGGLI: I would have to know that
15 anyway before I treated a patient again. Again,
16 because of the cumulative effect of bone marrow
17 exposure over a short period of time. I'd have to
18 know even if I didn't treat them, I would have to know
19 if they were treated in another facility. And I would
20 have to factor the effect of that treatment on the
21 patient's bone marrow into my calculation of a future
22 treatment.

23 So, again, I think that all rolls through
24 that it's not going to effect my practice to change
25 the regulation to reflect per year.

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1 DR. HOWE: Dr. Nag?

2 MEMBER NAG: I'm thinking of a new angle,
3 What if someone was taking care of a particular
4 individual and now has to take care of a different
5 individual, maybe the brother or maybe someone else in
6 the family, then you are likely to exceed and you
7 wouldn't know it because you did not treat the other
8 family member. How do we -- I mean what limit do we
9 give for those. I haven't thought about that until --
10 again, I think I haven't time to think about many of
11 these things.

12 CHAIR MALMUD: How this addresses.

13 DR. HOWE: I believe in this case the dose
14 to the other individual has to be from this patient.
15 Because it says, "the total effective dose equivalent
16 to any other individual from exposure to the released
17 individual."

18 CHAIR MALMUD: Yes.

19 DR. HOWE: So it doesn't take in a dose
20 received from another released individual, this
21 particular part of the regulation. Because it's
22 trying to determine why I can release this particular
23 patient.

24 CHAIR MALMUD: Mr. Lieto?

25 MEMBER LIETO: Well, I don't think the

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1 question got answered about are you talking calendar
2 year or 12 month period. Because it makes a
3 difference because keeping records and checking and
4 everything, it's just like occupational records, okay.
5 You don't do it from a May 1st to a May 1st; you do it
6 from a January 1st to December 31st. And so it does
7 make an issue if you've got individuals that are going
8 to get multiple therapies in a calendar year or in a
9 12 month period.

10 The second thing is hasn't NRC already
11 published something in their newsletter that went out
12 to licensees about this issue already stating that
13 this was the fact? There was something that's already
14 gone out. There was something along this line within
15 the last year where NRC has already stated that this
16 -- so I'm kind of wondering if you've already gone out
17 and told all the licensees this is the way it is, why
18 are you coming back to us?

19 DR. ZELAC: Can I speak to that? This is
20 Dr. Zelac.

21 CHAIR MALMUD: Dr. Zelac?

22 DR. ZELAC: I was the author of the
23 newsletter article to which you refer. And we
24 received an interpretation from our Office of General
25 Counsel that although the intent, as Donna-Beth had

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1 said, of the Commissioners is clear, the rule language
2 does not support that intent. So what we said is in
3 fact incorrect. The rule as written is not, and
4 cannot be interpreted on an annual basis.

5 There will be another newsletter article
6 coming out, hopefully, in the near future which will
7 make it clear that this issue continues to be under
8 discussion, but at the moment the regulation as
9 written cannot be supported on a per year basis.
10 That's the reason for this proposed change or
11 suggested change to the rule.

12 CHAIR MALMUD: I have a question for you,
13 Dr. Howe. Does this relate to outpatient therapy of
14 I-131? Is that where it came from?

15 MS. FLANNERY: Can I respond to this one?

16 DR. HOWE: Yes.

17 MS. FLANNERY: As far as this particular
18 case, this was a series of six administrations of
19 iodine-131 given over a period of a couple of weeks
20 time frame. And what was calculated is that each
21 release would result in a 250 millirem dose to a
22 member of the public for a total of 1.5 rem.

23 CHAIR MALMUD: Six I-131 therapies in --

24 DR. ZELAC: Not oral. Not oral iodine.

25 This was a labeled antibody, if I recall.

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1 CHAIR MALMUD: I see.

2 MEMBER VAN DECKER: That must have been an
3 investigational therapy.

4 MS. FLANNERY: That I don't know. This is
5 a question that came in from an agreement state, so I
6 don't know anymore detail than that.

7 CHAIR MALMUD: Mr. Lieto?

8 MEMBER LIETO: Well, I think this kind of
9 gets back to Dr. Suleiman's point about caregivers.
10 And I thought we had sort of a upper guideline of
11 around 2 rem in the information notice or regulatory
12 issue summary, whatever format it was in, that went
13 out on this.

14 So I would like to make a motion. I think
15 some of these have a lot more currents underneath them
16 than we're seeing right here. And I'd like to kind of
17 maybe take a look and get some more information on
18 these things before we make a judgment. Could I make
19 a motion that we maybe table all these until we get
20 some more background information on these proposed
21 changes? Because I think the more we talk about this
22 and go back and forth we see that there's more issues
23 than maybe we're seeing at first blush in discussing
24 these. And I'd like to move that we just --

25 CHAIR MALMUD: Mr. Lieto has made a motion

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1 to table this item. Is there a second?

2 MEMBER WILLIAMSON: He wants to table all
3 the items.

4 DR. HOWE: He wants table all the items.

5 MEMBER LIETO: I would table all these.

6 MEMBER WILLIAMSON: I would table this one
7 for sure, since we can't seem to get to the bottom of
8 it.

9 DR. HOWE: I would like to bring up one of
10 the items just so that you have it in mind for a later
11 discussion by Mr. Nag.

12 CHAIR MALMUD: What?

13 MEMBER NAG: One thing we can do instead
14 of tabling everything, we can go more at an
15 information item. Next, I would suggest let Donna go
16 through it as an information item without voting on
17 the issues. We can vote on the issues later.

18 MS. WASTLER: That's also a viable option
19 so that you could ask what questions you have, and
20 then any motion could come at a later time after
21 you've thought about the responses or --

22 MEMBER NAG: Because otherwise, you know,
23 if we don't go through it, later on we have to start
24 all over again. Here at least we can have an
25 introduction to the problem and that will allow us

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1 time to think about it at a later time. And if
2 needed, we can even do the motion on a telephone
3 conference call.

4 MEMBER SULEIMAN: I agree with what he's
5 saying.

6 MEMBER LIETO: I agree.

7 CHAIR MALMUD: Dr. Nag, thank you.

8 DR. HOWE: Sally?

9 CHAIR MALMUD: Yours is a motion that we
10 accept these as informational items. Is there a
11 second?

12 MEMBER SCHWARZ: Can I ask one more
13 question. Dr. Schwarz?

14 MEMBER SCHWARZ: I mean in terms of what
15 is being discussed, I mean it seems like there is
16 significant background for each of these issues that's
17 really -- you know, it's coming out from Ron and
18 Cynthia. And it would be helpful if rather than --
19 that it actually is presented, all the information
20 that's known about the case that brought it here to
21 begin with, rather than having to kind of piecemeal
22 add it in, it would be helpful for us.

23 CHAIR MALMUD: So are you seconding?

24 MEMBER SCHWARZ: Yes.

25 CHAIR MALMUD: All right. So Dr. Nag's

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1 motion to listen to all these as informational items
2 has been seconded by Sally. And any further
3 discussion of that motion? If not, all in favor of
4 the motion.

5 (Vote by show of hands.)

6 CHAIR MALMUD: Motion carries.

7 So, Donna-Beth, could you go on to the
8 next item?

9 MEMBER EGGLI: Well, actually, could I
10 pursue this current item just a little further, sir?

11 CHAIR MALMUD: Okay. Sure.

12 MEMBER EGGLI: What it sounds to me,
13 Cindy, is that this is really a caregiver exemption,
14 which is really different than this issue. That,
15 first of all, again it takes over 180 millicuries with
16 standard precautions to create a dose of more than 5
17 millirems. So we're talking about some kind of a high
18 dose therapy. And it sounds like the exemption being
19 asked for was the caregiver issue that we've discussed
20 in the past and not this same issue of the exposure to
21 the general public. And if you're going to put
22 together the information for this, I think it would be
23 very desirable to separate whether we're looking at a
24 caregiver exemption versus a concept of the exposure
25 to the general public in looking at this. Because I'm

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1 still having trouble imagining any standard
2 radioiodine therapy where you would give so much over
3 a short period of time that someone other than a
4 caregiver of a very ill person would get that kind of
5 exposure.

6 DR. HOWE: And you may also be looking at
7 you cannot have the normal assumptions that you have
8 when you release patients. There may be additional
9 care -- there may be additional close contact that
10 you're not anticipating.

11 MEMBER EGGLI: Right. But that would
12 probably fall under the caregiver exemption rather
13 than the general release role.

14 DR. HOWE: Right now the caregiver
15 exemption I believe is only in Part 20 for patients
16 that are hospitalized.

17 MS. WASTLER: No, Donna-Beth. They're
18 talking about the care --

19 MEMBER EGGLI: Yes. And I understand what
20 you're saying --

21 DR. HOWE: But I think the simulation is
22 what --

23 MS. WASTLER: Yes. Okay. You're right.

24 MEMBER EGGLI: I understand what you're
25 saying.

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1 MS. WASTLER: It is in relation to
2 hospitals. But, yes. But the concept may transfer?

3 DR. HOWE: Yes.

4 MEMBER EGGLI: Yes.

5 DR. HOWE: Okay.

6 MS. WASTLER: So we need to look at the
7 two together. Okay. I agree.

8 CHAIR MALMUD: Dr. Suleiman?

9 MEMBER SULEIMAN: Well NCRP if my memory
10 is right, commentary 11 addresses caregivers. And I
11 think some new ICRP guidance also distinguishes
12 caregivers from the general public. So I think this
13 issue has traction. And I think the NRC, it would be
14 good to sort of address caregivers and family members
15 and so on in a separate category. And I think it
16 would make life a whole lot easier for both the
17 patients and the users. Because the way that reads,
18 that's any individual. So that would preempt any
19 caregiver. That basically says anybody other than the
20 patient.

21 Some of this have always felt this was a
22 simple solution, but I think this is something that
23 should be addressed in a very clear manner, and I
24 think it would be good to find out what other
25 guidances or other agencies are doing.

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1 DR. HOWE: All right.

2 CHAIR MALMUD: Dr. Fisher?

3 MEMBER FISHER: There's a medical
4 rationale for protracting a high dose radio-
5 immunotherapy infusion. And what I think is
6 interesting here is that the regulations could prevent
7 a protraction of a high dose therapy where an infusion
8 is given, say, in six multiple infusions. Normally a
9 high dose radio-immunotherapy procedure such as
10 600/700 millicuries is given in a single dose. The
11 patient can be held in the hospital for a number of
12 days, seven or eight days, and then released.

13 It sounds like an investigator is trying
14 to give a high dose infusion over six different
15 infusions, which would cause, according to this rule,
16 that the patient could not be released over a long,
17 long period from a hospital. So I think we need
18 further background on this issue.

19 DR. HOWE: But you would also think that
20 one way to bring the dose down would be if he's giving
21 it over six different parts, he may hospitalize him
22 for a small period of time on each one, because that
23 brings the total dose down. But that's just another
24 way of looking at it. It's not saying you have to be
25 hospitalized for the entire time, but you might have

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1 -- if I could move on to my next one?

2 CHAIR MALMUD: Please do.

3 DR. HOWE: This is 35.491. And this
4 training and experience requirements for ophthalmic,
5 eye applicator devices. And this one I really want to
6 bring up now because Dr. Nag is going to be talking
7 about the new technology. And we looked at the --
8 it's a new technology. Our current experience when
9 the rule was written in 2002 and 2005 was the eye
10 applicator that was placed on the exterior part of the
11 eye. And the new use is where you actually go into
12 the eye with strontium device and treat inside the
13 eye.

14 We took a look at it and we thought that
15 there may be significant training issues that are
16 associated with it. And that it might be over in
17 35.1000 or we might want to revise the training
18 requirements in 35.491 to include this new device.

19 And so if in fact we decide -- Dr. Nag's
20 going to present a more in depth discussion of the
21 device itself and how it's used and what it does. And
22 our thinking was that if we were to go into 35.491, we
23 would want to distinguish between what is currently
24 done, and that's a superficial ophthalmic radiotherapy
25 procedure and a training and supervised work

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1 experience in this new intra-ocular ophthalmic
2 radiotherapy device. And we would consider the basic
3 radiation safety that is required in 35.491 to be the
4 same but that the supervised work experience would be
5 more particular to --

6 MEMBER NAG: My suggestion is that we
7 table the discussion of this after my presentation
8 when the ACMUI had their understanding of what this
9 new technology is. And you can bring up under the
10 discussion after my presentation. You know, I haven't
11 described --

12 DR. HOWE: And that's exactly what I
13 intended to do. Is just bring it up as we know it's
14 coming, we know Dr. Nag is going to talk in a lot more
15 detail about the device and you'll have a much better
16 idea of what you want to think about then. But just
17 to bring up that these were kind of our preliminary
18 thoughts, too.

19 MEMBER WILLIAMSON: Is this an
20 interstitial brachytherapy device?

21 MEMBER NAG: Well, we'll talk about it.

22 DR. HOWE: Yes.

23 MEMBER NAG: It penetrates inside the eye.
24 It's not superficial. It's not surface.

25 DR. HOWE: They pen the eye and insert the

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1 probe.

2 MEMBER WILLIAMSON: So maybe it would be
3 best to leave this in the hands of a radiation
4 oncologist.

5 DR. HOWE: So this is just to kind of
6 introduce you to the concept. Okay.

7 MEMBER WILLIAMSON: The 35.491 is for the
8 ophthalmologist, correct?

9 DR. HOWE: Yes.

10 MEMBER WILLIAMSON: To be able to perform
11 strontium 90 eye plaque therapy independently of --

12 DR. HOWE: Yes. And because 35.491 is
13 written in very general terms, it just talks about
14 ophthalmic radiotherapy treatment, but the terms
15 themselves are general enough to include this new
16 device. And the question is should this new device
17 really be included in 491. And that's going to be the
18 issue for you. And Dr. Nag will give you a better
19 perspective on what the device is.

20 So if I can move on --

21 CHAIR MALMUD: Thank you.

22 DR. HOWE: -- in 35.400, .500 and .600,
23 which are sealed source and devices we require
24 licensees to only use the sealed sources and devices
25 in these sections as approved in the sealed source and

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1 device registry. This creates some issues for us.

2 The manufacturers will indicate uses for
3 their devices and sources. Those uses may not be all
4 encompassing, they may be presented much earlier in
5 the sealed source and device registry history. They
6 may be out of date. And the individuals that are
7 doing the sealed source and device registry are not
8 really looking at the medical use. They're looking at
9 it as examples of ways the source and the device can
10 be used. And so we think it is inappropriate to tie
11 medical users to only -- to only use the sealed
12 sources and devices as approved in the sealed source
13 and device registry. And it came up recently with the
14 gamma knife Perfexion. Because the gamma knife
15 Perfexion is slightly different. It can encompass a
16 larger area for treatment, and yet the manufacturer
17 wrote in a very narrow limit. And our regions said
18 well that means any use outside of that because it's
19 not in accordance with the sealed source and device
20 registry is research. And we're trying to say no,
21 that's practice of medicine and we'd like to try to
22 address the problems with this particular requirement
23 in such a way that we can use the sealed source and
24 device registry for the reason it was intended, which
25 was the radiation safety aspects of the device or

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1 source and not get into the practice of medicine
2 issues.

3 And so I don't have any specific wording
4 for this. I just have a concept that somehow we
5 revise these particular sections to exclude the
6 specific medical indications provided by the
7 manufacturer while retaining the type of medical use,
8 manual brachytherapy, gamma 9, HDR, something like
9 that, the large grouping.

10 MEMBER NAG: I think this is something
11 that I would be -- you know, I would be attracted very
12 much about, and therefore I would like some time to
13 think about it.

14 I do not want to be restricted, that just
15 because they showed it would double up for treatment
16 of prostate cancer, you know, I can't modify and pre-
17 rectal cancer, too. I want to digest this a little
18 bit.

19 DR. HOWE: We don't want him to be
20 restricted. When they wrote the rule in 2002 they
21 thought this was a basket that would answer
22 everything. And we tried to point out that there
23 would be -- people might interpret this as restrictive
24 medical use, and we did not want that.

25 CHAIR MALMUD: Thank you. That completes

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1 your information items?

2 DR. HOWE: Yes.

3 CHAIR MALMUD: Thank you.

4 Sandi?

5 MS. WASTLER: Oh, I was just going to
6 point out that we are behind schedule. And we were
7 scheduled for a break at 9:30, so I would offer that
8 maybe it might be a good time to go ahead and take a
9 break.

10 CHAIR MALMUD: Yes. Thank you.

11 MEMBER NAG: Yes.

12 CHAIR MALMUD: Dr. Williamson would like
13 to offer a brief parting comment.

14 MEMBER WILLIAMSON: Yes. I think these
15 particular issues to give opinions on for proposed
16 rulemaking or concepts of rulemakings are especially
17 complicated. We do have to render some sort of a
18 decision or opinion. So unlike maybe some
19 informational items where we really don't have to
20 react so specifically, it might really be a good idea
21 to try to get these out more in advance.

22 MS. WASTLER: Oh, well I already have that
23 done as an action item that in the future anything
24 along these lines, and we do have these. I mean,
25 granted, we had a long discussion yesterday about

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1 implementation issues. But as we work through things,
2 we get, you know, here's a tweak, here's a problem.
3 And so we have to come to the Committee to vet those
4 to make sure that we're moving in the right direction
5 and that in the future we'll make sure that you get
6 those ahead of time and provide any background
7 information that might benefit you in making your
8 determination or benefit the discussion.

9 CHAIR MALMUD: Thank you. Can we resume
10 at 10:00? Fifteen minutes. Thank you.

11 (Whereupon at 9:43 a.m. a recess until
12 10:05 a.m.)

13 CHAIRMAN MALMUD: Can we get started,
14 please? We have a very extended agenda for the day.

15 MS. WASTLER: Dr. Malmud, if I could, I
16 would like to just take this opportunity to welcome
17 Dr. Bruce Thomadsen, who has joined us today. He
18 wasn't available yesterday. He is going to be the
19 ACMUI medical physicist in the next year. And
20 basically his full membership is still pending his
21 security clearance, but I just thought we would take
22 this opportunity to welcome him.

23 MEMBER THOMADSEN: Thank you.

24 CHAIRMAN MALMUD: Thank you. Welcome, Dr.
25 Thomadsen.

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1 MEMBER THOMADSEN: Thank you.

2 CHAIRMAN MALMUD: And your home base is?

3 MEMBER THOMADSEN: University of
4 Wisconsin.

5 CHAIRMAN MALMUD: There's another
6 Wisconsinite here.

7 (Laughter.)

8 MEMBER WELSH: I know him.

9 MEMBER NAG: By the way, could you --

10 MEMBER NAG: Would you clarify what
11 Bruce's status will be at this meeting? Is he an
12 observer?

13 MS. WASTLER: He is.

14 MEMBER NAG: Can he vote? What will it
15 be?

16 MS. WASTLER: I believe that he is a
17 nonvoting member --

18 MEMBER NAG: Okay.

19 MS. WASTLER: -- because his full ACMUI
20 membership won't be established until he completes the
21 security clearance. But right now, yes, he will be
22 Jeffrey Williamson's replacement in the therapy
23 medical physicist position.

24 MEMBER NAG: Yes. I just wanted to
25 clarify.

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1 MS. WASTLER: No problem. Thank you.

2 CHAIRMAN MALMUD: If we may, we will move
3 on to the next item on the agenda, which I believe is
4 Mr. Lieto.

5 MEMBER LIETO: Thank you, Mr. Chairman.

6 10. ONE RSO ON LICENSE

7 MEMBER LIETO: One thing I just kind of
8 wanted in terms of, I guess I should say, some
9 background information, I regret that Dr. Vetter is
10 not here since he is the RSO member, but I would like
11 to point out that he has seen my slides and had the
12 opportunity to comment and improve on them, hopefully.
13 And so he is fully aware of the content of this
14 presentation.

15 So, with that, I want to address the issue
16 of why only one RSO on a license, not so much maybe
17 the history of this but sort of what my impressions
18 are on it, but also the current situation and maybe
19 provide some discussion that we might be able to come
20 to some resolution on, maybe not at this meeting but
21 at least establish as a future agenda item with some
22 action that the Committee can take on this issue.

23 In researching this, some of the things
24 that have come to my attention are that there is only
25 one RSO that is issued on a license. And I believe

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1 that's true also in agreement states, but I may be
2 wrong. But I will speak definitely as a non-agreement
3 state, an NRC state medical physicist, and an RSO that
4 there is only one listed on the license, but it's not
5 required by regulation. There's no regulation that
6 says you have to have only one RSO on the license.

7 In trying to find some background
8 information as to why is there only one RSO on a
9 license, neither NRC staff at headquarters or in the
10 region that I inquired was able to provide any
11 information as to a policy statement that exists why
12 there is only one RSO on a license. There is not any
13 Office of General Counsel statement or policy or NRC
14 document to this.

15 So I've kind of made some suppositions on
16 this and that looking back at licenses that I've been
17 involved with that go back a few decades, that the
18 officer concept probably suggests an old AEC or
19 military-origin concept of a singular person with
20 duties for radiation safety for a facility or area.
21 And I think that is just carried over.

22 There may have been a written policy to
23 this extent directing this, but, again, there does not
24 appear to be anything in writing that exists regarding
25 such a policy.

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1 The other thing that I wanted to point out
2 from a background standpoint is that the existence of
3 a singular RSO predates the NRC establishment of
4 management being responsible for radiation safety
5 programs.

6 That largely came about, I believe, in the
7 late '80s or early '90s. And I'm sure if I am wrong,
8 NRC staff will correct me. But that was about the
9 time frame where management really became the focus
10 for the responsibility for radiation safety programs.

11 Current regulations that address Part 35
12 are found in section 12. You have to submit the
13 training and experience and qualifications for a
14 radiation safety officer when you apply for a license
15 or renew a license or make an amendment that
16 specifically addresses the radiation safety officer.

17 The amendment changes are addressed in
18 section C of section 13, which states that you are to
19 make that amendment change for an RSO before changing
20 RSOs except as provided in section 24(c), which I will
21 get to in a second.

22 Section 24 addresses the responsibilities
23 and authority of the radiation safety officer under
24 the program. It states that the RSO is appointed by
25 management, the RSO has to agree in writing with

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1 management that they will be responsible for the
2 program on a routine basis and that basically the RSO
3 is the licensee management's proxy for the performance
4 of the radiation safety program to comply with
5 regulations and license conditions.

6 Now, one point I wanted to make and bring
7 to the Committee's attention is that in section
8 35.24(c), which addresses the authority and
9 responsibilities under the program, it allows under
10 regulation for a temporary RSO for up to 60 days.

11 And it states that the licensee can
12 authorize or permit an AU or an individual who meets
13 the RSO qualifications to be the RSO for up to 60 days
14 in a calendar year. And this is what they categorize
15 as a temporary RSO and some other things that the
16 licensee has to meet which are already in place. And
17 they have to notify the NRC within 30 days that they
18 have made this temporary appointment.

19 Now, nothing changers on the license.
20 Okay? There's no record of this that goes anywhere
21 other than simply a notification to the NRC office or
22 I'm assuming the agreement state radiation control
23 office.

24 It also permits up to 60 days the
25 simultaneous appointment of more than one temporary

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1 RSO in accordance with the 24(c) that you see in the
2 top paragraph there. And it says that the management
3 can do this, if needed, to ensure that the licensee
4 has radiation safety officer coverage in the
5 appropriate area.

6 So obviously if you have a multi-modality
7 with maybe HDR and radiopharmaceutical therapy and
8 diagnostic applications, you might have multiple
9 individuals with temporary RSO responsibilities but,
10 again, remembering that the RSOs that are temporarily
11 appointed are notified to the NRC or the agreement
12 state office and that they're allowed to do this for
13 a two-month stint.

14 Now, looking at the guidance under the
15 NUREGs that address the radiation safety officer, this
16 is the guidance that is given to licensees as they
17 submit license applications or renewals or so forth in
18 complying with the sections that I just addressed.

19 It states that the RSO is responsible for
20 the day-to-day oversight of the program. It permits
21 consultants to perform these responsibilities. It
22 also indicates that it does not need to be a full-time
23 employee, even for a broad-scope license.

24 Now, I think some of us may have a little
25 bit of heartburn with that, but under the guidance

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1 document, that would be permitted. And there might be
2 certain circumstances maybe with limited broad scopes
3 that that might be appropriate or so forth. But,
4 nonetheless, it is permitted and then that it meets
5 the qualifications and "is available for advance and
6 assistance on radiological safety matters." So
7 obviously this guidance is used in the case of
8 consultants where they're not needing to be on site
9 for the day-to-day oversight activities.

10 Now, who is allowed to be or who currently
11 can have multiple listings on licenses? Well,
12 obviously your authorized users' positions have their
13 multiple authorized users. You could have multiple
14 AMPs on a license. You can have multiple authorized
15 nuclear pharmacists on the license.

16 At one time I know for a fact that NRC
17 regions were designating multiple RSOs on licenses,
18 but that has since been discontinued. So obviously
19 there may have been a policy or some type of statement
20 or guidance from headquarters that allowed this as a
21 possibility to be done.

22 Now, who isn't specified on the license?
23 Well, management isn't. They have the ultimate
24 responsibility for the radiation safety program and
25 are not named. They're not named by office. They're

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1 not named by individuals' names. They're not named by
2 title. Okay? So the people that have the real
3 ultimate responsibility for the program are not listed
4 anywhere.

5 Also not listed are health or medical
6 physicists, technologists, technicians, who may have
7 the actual daily program duties and responsibilities
8 for compliance. This obviously could range from a
9 very small imaging facility that would have maybe a
10 single authorized user and a single technologist or
11 the authorized user may or may not be there on a daily
12 basis.

13 Yet, the day-to-day management and
14 responsibilities fall to a technologist or technician
15 up to maybe very large programs under multi-modality
16 broad-scope medical licensees, where you may have a
17 staff of health physicists, who again cover all the
18 areas, have day-to-day responsibilities, but, again,
19 are not listed because of the RSO is the manager of
20 that program.

21 So what are some of the issues and
22 concerns that have been raised regarding the issues
23 revolving around having just a singular RSO named on
24 a license.

25 Well, obviously if you had multiple RSOs

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1 designated by area of expertise, there could result in
2 areas where there is commonality of responsibility and
3 you end up sort of getting this finger-pointing,
4 "Well, it's the other guy who is supposed to be taking
5 care of that."

6 And NRC at the regional level has
7 indicated that this was a problem in some licensees,
8 resulting in citations and I think maybe was some of
9 the impetus in going away for maybe the previous
10 situations, where multiple RSOs by area were listed.

11 I also know that in certain types of
12 broad-scope licenses, where you had large research
13 programs and medical programs, there may have been a
14 research RSO and a hospital/medical center RSO. And,
15 again, areas of commonality under the program, there
16 may have been some deficiencies that occurred and
17 concerns by NRC licensing staff with this type of a
18 problem.

19 Licensees also have expressed concerns and
20 issues on the singular side because they have staff
21 who perform these duties, meet the qualifications.
22 Yet, these qualified individuals are not named on the
23 program.

24 And also with the current T&E
25 interpretations of boards and the recentness of

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1 training, you could have individuals that have been
2 with a program for many years not listed, done the
3 duties, leave the program to be an RSO. Yet, they
4 have never had the RSO designation and have to go
5 through this whole documentation route, yet have
6 actually been performing the duties.

7 Other problems also that arise that, you
8 can't automatically replace an RSO if they leave,
9 either due to illness, extended leave for personal
10 reasons, that you don't have this very, shall we say,
11 quick, automatic change of who is listed on the
12 license.

13 Some other concerns with having a singular
14 that increasingly with small medical licensees,
15 100-200-type licensees, the situation is occurring
16 where you are having a single RSO listed on multiple
17 licensees.

18 So obviously this was -- I think this was
19 brought up yesterday by I think a member of the
20 audience and commented by Dr. Fisher that basically
21 what happens is you are diluting this individual and
22 performing the "day-to-day oversight" activities that
23 need to occur and that basically they're available to
24 provide assistance on more emergent radiological
25 matters, rather than day-to-day situations.

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1 And also by the fact that you're allowing
2 one individual to be on more and more licenses,
3 you're, shall we say, not bringing in new RSOs to fill
4 the pool that might be needed.

5 I think this problem is going to become
6 exacerbated by the fact that authorized users are
7 reluctant to be named on the license as an RSO for the
8 reasons that practices are now covering more areas.
9 They're rotating to more sites, having more clinical
10 responsibilities, and don't want to have the
11 responsibility of the RSO.

12 And also with the fact that doing more and
13 more duties, be it teleradiology, PAX-types operations
14 in this digital age, your fine physicians are at one
15 site and can cover from the standpoint of clinical
16 interpretation many more sites than were possible just
17 a few years ago.

18 So what are some suggestions? One
19 suggestion we thought that the NRC should consider and
20 ACMUI is the listing of the temporary RSO on the
21 license. And that should be under some other
22 designation to resolve the hierarchy concerns that
23 previously existed by NRC or were indicated by NRC
24 staff before.

25 In other words, you would have an RSO.

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1 And you would have this other individual with some
2 other designation. I like the term "radiation safety
3 specialist," but some other terms that have been
4 suggested are "associate RSO," sort of using the
5 academic type of hierarchy of full professor,
6 associate professor.

7 You would have the RSO and associate RSO
8 type individuals such that if the RSO left the
9 institution or was going to be gone for weeks at a
10 time, that it was obviously by management designation
11 because of this situation that the associate RSO could
12 fill in and there would not need to be any concerns
13 about coverage and monitoring on a day-to-day basis.

14 Another point that should be made is that
15 if you have an individual that meets the RSO
16 qualifications as a temporary RSO and has qualified to
17 do it for two months, why not just recognize them
18 altogether and put them on a license?

19 The fact that someone can cover a licensee
20 for two months at a time while meeting the RSO
21 qualifications, yet the only thing that occurs is a
22 notification to the regulatory office really I think
23 is not productive and would address those issues where
24 you might have multiple individuals that meet RSO
25 qualifications and it doesn't require a regulatory

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1 change.

2 Also maybe go back to permit listing of
3 these other RSOs, again maybe radiation safety -- the
4 term used here is "radiation safety specialist" -- and
5 designating the area of where they would have
6 radiation safety responsibilities, especially your
7 high-risk areas. That's what you want really covered.

8 I think 100 and 200 -- hopefully the
9 Committee would agree with me -- really are not areas
10 of high risk. Basically it's your radiopharmaceutical
11 therapy, your brachytherapy, and 600 applications.

12 There's obviously the need for a
13 documented policy. Now, I don't know if this needs to
14 come from the Office of General Counsel regarding some
15 written interpretation, but obviously there needs to
16 be a documented policy from headquarters level down to
17 the regions and hopefully with input of the agreement
18 states -- and I think ACMUI needs to be involved in
19 this -- that would authorize that the multiple RSOs be
20 listed on licenses and that there be some hierarchy
21 designation to indicate that there's sort of a
22 top-down responsibility for the management of this
23 program.

24 The last item I have here, replacing
25 "officer," is just sort of a pet peeve of mine that it

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1 sort of has this policeman-type attitude or
2 designation, which I don't think anybody that has ever
3 been listed as an RSO likes.

4 Some people maybe like to carry a big
5 black baton and wear dark boots. I don't know.

6 (Laughter.)

7 MEMBER LIETO: But I have never liked to.
8 I never liked the term, and I don't know if it could
9 be changed because it is so firmly ingrained into the
10 history of regulatory space, but those are my
11 suggestions on maybe addressing the multiple RSO
12 situation without requiring regulatory change.

13 CHAIRMAN MALMUD: Thank you.

14 Sandi, you wanted to say something?

15 MS. WASTLER: I just wanted a
16 clarification. So my understanding of what you are
17 saying is that on any one license, there would be one
18 RSO, who, as you I think stated, would be management's
19 proxy that's responsible for all the radiation safety.

20 And underneath him would be in a
21 hierarchical manner maybe temporary RSO, whatever the
22 term, assistant RSO. And those assistants could be
23 broken down by specialty, HDR, whatever, based on
24 their background or could actually be someone that
25 could cover multiple.

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1 MEMBER LIETO: I mean --

2 MS. WASTLER: I mean, is that the thought
3 pattern?

4 MEMBER LIETO: Yes, that's the thought.
5 I think if someone is authorized for the high-risk
6 areas, say like radiopharmaceutical therapy, you know,
7 the 100s and 200s would fall under that automatically,
8 the same thing for brachytherapy.

9 I think that if you have the
10 qualifications for radiation safety with
11 brachytherapy, I think that you have the training and
12 experience for being capable assuming they know the
13 regulations and so forth, being the RSO to manage the
14 radiation safety program for nuclear medicine imaging.

15 CHAIRMAN MALMUD: Jeff?

16 MEMBER WILLIAMSON: The listing of these
17 associate RSOs in the license, would they just be like
18 listed as associate RSO, period, or would it specify?
19 Would it be hardwired into the license document itself
20 what their scope of --

21 MEMBER LIETO: Yes.

22 MEMBER WILLIAMSON: Is that desirable or
23 necessary?

24 MEMBER LIETO: Well, I guess I would leave
25 that open for discussion, but the person and the

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1 designation would be hardwired, would be listed
2 physically on the license.

3 CHAIRMAN MALMUD: Dr. Nag?

4 MEMBER NAG: This is just semantics, but
5 my suggestion would be that anyone who qualified to be
6 an RSO by whatever, 35-50, whatever, would be called
7 an RSO. There can be multiples of them. And then the
8 one who links with the management or the one who will
9 oversee all the operation in a big institution that
10 will have many RSOs would be called the chief RSO.

11 (Laughter.)

12 MEMBER NAG: No. But the thing is that
13 anyone who is an RSO could qualify to be the certified
14 person, you know, could be doing anything that the
15 other RSO is doing. So that would possibly solve the
16 shortage of RSOs.

17 So you still call them RSO. They are not
18 assistant to anything. They are RSO. But the one who
19 is overseeing the whole operation would be named the
20 chief RSO and linked to the administration.

21 CHAIRMAN MALMUD: Doug?

22 MEMBER EGGLI: I like the concept of
23 associate RSO. And anyone who meets the
24 qualifications to be an RSO could be potentially then
25 listed on a license as an RSO.

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1 As far as the "O" part, the officer part,
2 it is ingrained in not only NRC but in corporate
3 governance. There is a chief executive officer, a
4 chief operating officer, a chief financial officer, a
5 chief information officer.

6 The term "officer" in this case implies
7 someone who has a responsibility for a sphere of
8 activity and governance. So I don't have a problem
9 with the RSO term, but allowing the designation of
10 associate RSOs then solves the preceptor problem.

11 I would hardwire the names of those
12 individuals onto the license applications, but I would
13 be very reluctant to see a sphere of responsibility
14 for that associate RSO hardwired into the license
15 application and allow them, the institution, by
16 internal policy to either have an associate RSO who
17 covers everything that the RSO does or to assign
18 spheres of responsibility within an institution. But
19 I think it's a good idea to hardwire those spheres of
20 responsibility over the license applications.

21 MEMBER LIETO: You don't?

22 MEMBER EGGLI: I would not hardwire the
23 description of the responsibility. I would hardwire
24 the associate concept and the name of the person but
25 not the sphere of responsibility.

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1 CHAIRMAN MALMUD: Dr. Williamson?

2 MEMBER WILLIAMSON: Yes. I like Dr. Nag's
3 suggestion of calling all of the RSOs RSOs because
4 that is transparent. It doesn't require changing the
5 rule language anywhere else in the regulation. We
6 only have to be changed in one place that does have
7 some sort of a designated or executive RSO that would
8 actually have overall responsibility for the license.

9 And I also agree with Dr. Eggli's
10 suggestion that the function not be hardwired and the
11 like.

12 CHAIRMAN MALMUD: We have Dr. Suleiman?

13 MEMBER SULEIMAN: I also think the concept
14 is good. I would prefer senior RSO.

15 (Laughter.)

16 MEMBER SULEIMAN: I would let the
17 associate thing drop, either way. But, rather than
18 try to categorize it by class of product because you
19 may have departments that may have multiple modalities
20 and so on, I would try not to bind that into some sort
21 of a regulatory hierarchy so that it would be
22 clarifying and useful to the facilities, to the
23 licensee to show that this RSO or associate RSO is
24 responsible for radiology or nuclear medicine or
25 oncology or endocrinology, I mean, whenever they may

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1 be using radioactive materials.

2 And that may very well vary from site to
3 site. But at least it would probably be much more
4 clarifying for the licensee.

5 MEMBER LIETO: A further thought. It's
6 probably a good point because if you did hardwire it
7 by sphere, if you wanted to change it, you would have
8 to go back and amend the license.

9 MEMBER SULEIMAN: Oh, absolutely. I can
10 see where we're --

11 MEMBER LIETO: And I don't think you would
12 want to. I think you want to try to avoid that as
13 much as possible.

14 MEMBER SULEIMAN: I always ask people what
15 department. And I get a different answer almost every
16 time. So most institutions are structured very
17 differently.

18 MEMBER LIETO: Good point.

19 CHAIRMAN MALMUD: Member of the public?

20 DR. BROGA: Dr. Broga. Up until the late
21 '90s, at least in Region 2, the NRC named all RSOs on
22 licenses, dozens of licenses, listed them, and
23 required the same submission documentation from the
24 management as was for the RSO.

25 Somewhere in the late '90s, a decision was

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1 made from the NRC to stop allowing alternate RSOs to
2 be listed on licenses. I don't know the reason for
3 it, but there was at least a decade of history of
4 alternate RSOs being named on licenses.

5 CHAIRMAN MALMUD: Does anyone know why
6 that practice stopped?

7 MS. WASTLER: I think, unfortunately, as
8 Mr. Lieto said, that many of us weren't here. And we
9 have not been able to locate any document that
10 specifically says.

11 But that's a good point. You said Region
12 2?

13 DR. BROGA: Yes.

14 MS. WASTLER: Did you talk to Region I?

15 MEMBER LIETO: I talked to Region 3 and
16 they --

17 MS. WASTLER: Three? We might be able to
18 get some more information, maybe going to Region 2.
19 I think we need to obviously look into this a little
20 more, but I am not aware. And I checked with my
21 touchstones, Donna-Beth and Ron, who have been with
22 the program for a lot longer.

23 And I'm not sure that any of us are aware
24 of any policy statement. So, you know, why the
25 decision was made at this point I can't tell you. It

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1 may be buried in some of the enforcement cases, you
2 know, that it came out of and where there was no -- as
3 you said, there is nothing in the regulations that
4 says you can't do it. The reverse is it does not say
5 that you cannot.

6 So, you know, someone had made a decision
7 for some reason. And more than likely, my inclination
8 would be it's related to some kind of enforcement
9 problem that the decision was made.

10 And because there wasn't any requirement
11 for any change from a regulatory standpoint, it was
12 kind of part of the process just got incorporated in
13 the way we do business. And, unfortunately, it wasn't
14 documented.

15 CHAIRMAN MALMUD: Dr. Thomadsen?

16 MEMBER THOMADSEN: I would have to check
17 to make sure, but I believe that we had our associate
18 RSO listed on our license. I remember we sent in an
19 amendment for that.

20 MEMBER GILLEY: Is this to Wisconsin?

21 MEMBER THOMADSEN: Yes, right. So at
22 least I think one agreement state does do that.

23 MEMBER GILLEY: I think we had one in
24 Florida, but I couldn't speak for all of the agreement
25 states because they are all different. But we do

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1 corporate RSO. And then we let you include
2 site-specific RSOs in the application you submit to
3 us.

4 So in some of the broad-scope licenses,
5 they have an assistant RSO at each facility. We have
6 14 or 15 facilities in the State of Florida. So they
7 would as part of their application or renewal process
8 submit that in, which is, of course, included in the
9 catch-all or the last statement of the license. So
10 there already is some flexibility.

11 But they're not specifically listed on the
12 license. The information submitted becomes legally
13 binding.

14 CHAIRMAN MALMUD: Member of the public, I
15 believe, is waiting.

16 MEMBER SCHWARZ: Maybe Linda is --

17 MS. FAIROBENT: Lynne Fairobent, AAPM.
18 Unfortunately, I am going to truly date myself now.

19 (Laughter.)

20 MS. WASTLER: I would have to admit that
21 only Lynne and I go back too many years. So you are
22 dating both of us.

23 MS. FAIROBENT: In 1977 and '78, when I
24 was in the Region 3 office, we did back then have more
25 than one RSO on a license. In 1979, when I came to

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1 headquarters to licensed materials programs, again it
2 was allowed.

3 I think part of the change came about --
4 and I probably do have documents, unfortunately, in my
5 garage or basement because I'm a pack rat. But after
6 TMI, there were a lot of discussions in the nuclear
7 power industry about strengthening the role of the
8 radiation safety officer in commercial nuclear power
9 plants.

10 And there was an awful lot of discussion
11 and flow-down from that in the 1980s and late '80s.
12 And when I was with the Nuclear Energy Institute in
13 the middle '80s, a lot of these changes came about in
14 the power industry and agreeing to give and
15 acknowledge the authority and responsibility to the
16 radiation safety officer to shut down a nuclear power
17 plant.

18 I think around that same time, which would
19 have been late '80s, early 1990s that Dean is
20 referencing, some of this just trickled down across
21 the agency for consistency.

22 I don't know that there was any real
23 policy statement that did this, but there certainly
24 was general discussions amongst the community for
25 consistency of what was being done across all licensee

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1 categories.

2 We can talk afterwards, Sandi, but I may
3 be able to help point in some directions. But, like
4 I said, I do know originally back in the late '70s, we
5 did have multiple RSOs, at least in Region 3 and then
6 from headquarters, when we at that time were doing all
7 of the licensing except for the pilot program in 3
8 back in '78-'79.

9 So I think it's just been historical
10 changes but no real regulatory hard hammer or meat
11 behind the justification to do that.

12 MS. WASTLER: No real policy paper but
13 just, you know, the concept floating down.

14 MS. FAIROBENT: Right. And I think if you
15 go back and look at some of the old statements and
16 considerations for some of the amendments that
17 predated the wholesale revision to Part 35, you may
18 actually find some bits and pieces, but those records
19 are --

20 MS. WASTLER: It might be buried, really
21 buried.

22 MS. FAIROBENT: -- probably buried and
23 hard to extract that data.

24 MS. WASTLER: Yes.

25 MS. FAIROBENT: But that is where I

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1 suspect that it may be hidden.

2 MS. WASTLER: Okay. Thank you.

3 CHAIRMAN MALMUD: If I may? Excuse me.

4 Dr. Fisher?

5 MEMBER FISHER: Just a quick question.

6 What is the current practice of the NRC if it receives
7 a license application listing two names as RSO?

8 MEMBER GILLEY: I can speak for the State
9 of Florida. We would send it back and say you needed
10 to identify the RSO.

11 MS. WASTLER: The RSO. I think that it
12 would be the same thing for us. You would have to
13 name an RSO. And that RSO would be the only one that
14 would be put on the license.

15 You might have to list it. But as soon as
16 you said Joe X is the RSO, that's the person that
17 would be put on --

18 MEMBER FISHER: So if two names were
19 listed on the application, it would be sent back?

20 MS. WASTLER: No. Well, I can't
21 necessarily speak. Donna-Beth, are you aware of
22 whether they send the application back or -- licensing
23 is done in the region.

24 DR. HOWE: I don't think they necessarily
25 send the application back, but there is a request for

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1 additional information. The request for additional
2 information is, who is your RSO?

3 MS. WASTLER: Right.

4 DR. HOWE: You have given us two people.
5 Which one is it?

6 MS. WASTLER: Right. And basically, I
7 mean, your application might have five RSOs listed,
8 but only the senior, top, executive RSO would be the
9 one that would be on the license.

10 CHAIRMAN MALMUD: Ralph, in summary, then,
11 would it be acceptable to you for someone to make a
12 motion that there be more than one RSO permitted per
13 organization, that there be -- obviously for
14 management, there has to be one person in charge. So
15 that the others might be called associate RSOs,
16 leaving the term "RSO" intact. Too many changes at
17 one time might bring rejection.

18 So that there would still be a designated
19 RSO. And others would be listed on the license as
20 associate RSOs with recognition that their roles as
21 associate RSOs qualify them for application to other
22 institutions having had RSO experience.

23 Would that cover the spirit of what you
24 wanted to get across?

25 MEMBER LIETO: Yes. And a documented

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1 policy by NRC of guidance to its regions for that. I
2 think there needs to be some written --

3 CHAIRMAN MALMUD: The request of
4 documentation of policy. All right. So if the
5 recommendation is that there be more than one RSO per
6 institution, there would still be an RSO who is the
7 senior RSO designated as the RSO. The others would be
8 associates with a request from the NRC for a policy.
9 That's a motion, your motion?

10 MEMBER LIETO: It can be.

11 CHAIRMAN MALMUD: Seconded by Dr. Schwarz.
12 Is there any discussion of the motion? Dr.
13 Williamson?

14 MEMBER WILLIAMSON: Yes. I would be
15 careful about locking the motion into specific
16 terminology, such as, as you have phrased it, RSO
17 versus associate RSO. It might be better and more
18 straightforward to amend the regulations if it's chief
19 RSO versus RSO. So I think you should leave it open.

20 CHAIRMAN MALMUD: Okay. That sounds
21 reasonable as long as --

22 MEMBER WILLIAMSON: The concept is one has
23 to be designated as --

24 CHAIRMAN MALMUD: Somebody has to be in
25 charge, right.

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1 MEMBER WILLIAMSON: -- the RSO of record.

2 CHAIRMAN MALMUD: Right.

3 MS. WASTLER: As Mr. Vetter noted, this
4 policy is implementation of existing regulations.
5 There is no change that will be taken. It's simply a
6 reinterpretation of the existing policy. And the
7 policy statement would define the terms per se.

8 MEMBER WILLIAMSON: Well, this is the
9 concern why I suggest the term "RSO" be left intact.
10 Otherwise I'm afraid it might be subsequently
11 interpreted that associate RSOs cannot be preceptors
12 for RSOs.

13 MEMBER NAG: I would like to amend the
14 motion.

15 CHAIRMAN MALMUD: Please do.

16 MEMBER NAG: The amended motion would be
17 that multiple RSOs be allowed on the license and that
18 one of those RSOs be identified to be the RSO in
19 charge. So don't use associate or anything like that.

20 And, you know, you can call them whatever
21 you like, chief RSO, RSO in charge, senior RSO. You
22 can name whatever you want, but all of them are RSOs.
23 One of them is the one who is put down.

24 You know, just like a department has many
25 radiation oncologist, but one is a chief radiation

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1 oncologist.

2 CHAIRMAN MALMUD: Dr. Suleiman?

3 MEMBER SULEIMAN: I second the motion.

4 CHAIRMAN MALMUD: The motion will state
5 that there will be more than one RSO at an institution
6 with a designation of one of the RSOs as the person in
7 charge.

8 MS. WASTLER: The first motion is off the
9 table now? Oh, it was amended. Okay.

10 CHAIRMAN MALMUD: It will be amended with
11 the approval of the --

12 MS. WASTLER: It was a friendly amendment?

13 CHAIRMAN MALMUD: Was that with your
14 approval?

15 MEMBER LIETO: I have no -- yes, I would
16 agree.

17 CHAIRMAN MALMUD: Dr. Suleiman, it's with
18 your approval? All right. It's been amended. Do you
19 wish to amend the amendment?

20 MEMBER SULEIMAN: No.

21 (Laughter.)

22 MEMBER SULEIMAN: Are we discussing it?

23 CHAIRMAN MALMUD: Sure. I mean, you've
24 got it. You got what you just asked for.

25 MEMBER SULEIMAN: I think it's a perfect

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1 solution. I'm just curious. Does anybody see
2 something wrong with it?

3 MS. WASTLER: As we say, the devil is in
4 the details, but --

5 MEMBER SULEIMAN: But if something is
6 obvious, let them speak now.

7 (Laughter.)

8 CHAIRMAN MALMUD: I mean, we could table
9 it and give them time to think about it. That was
10 meant to be in humor.

11 (Laughter.)

12 CHAIRMAN MALMUD: All right. Sally?

13 MEMBER SCHWARZ: I just have a question.
14 Since it will be a matter of our minutes of this
15 meeting, I mean, will it be written anywhere that it
16 would become like guidance document, I mean, such
17 that, you know, it actually will happen?

18 CHAIRMAN MALMUD: Yes because I understood
19 that this really is not a change in policy. This is
20 just the ability to designate more than one RSO at an
21 institution for purposes of labeling them as RSOs,
22 still identifying one of those RSOs as the person in
23 charge.

24 MS. WASTLER: We would have to obviously
25 put together some document, choose the appropriate

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1 vehicle, but because it isn't a change in the
2 regulation, it is an interpretation, it would probably
3 be some kind of generic communication that would have
4 to obviously go through OGC.

5 MEMBER GILLEY: Could you do this as an
6 information notice?

7 MS. WASTLER: It's a RIS. I have to look
8 at my experts. I always get them mixed up. Basically
9 a RIS is just a general clarification document.

10 CHAIRMAN MALMUD: Was there another
11 comment?

12 MS. WASTLER: One thing I was going to
13 raise was, did the Committee want to put together a
14 subcommittee and participate in the development of
15 this document?

16 MEMBER NAG: Which? RSO or which document
17 are you talking about?

18 MS. WASTLER: The one we were talking
19 about just now, for the RSO, the policy statement or
20 document. I'm simply raising it --

21 CHAIRMAN MALMUD: With all due respect, I
22 think that we have made a recommendation.

23 MS. WASTLER: Okay.

24 CHAIRMAN MALMUD: It is going to be the
25 OGC who eventually blesses this or not.

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1 MS. WASTLER: Yes.

2 CHAIRMAN MALMUD: And then it will be a
3 memo coming out of NRC staff. I don't know that we
4 need a subcommittee to do that.

5 MS. WASTLER: Okay.

6 CHAIRMAN MALMUD: But we still haven't
7 voted on this. So may I call for the vote?

8 MEMBER NAG: I think there are still some
9 questions or comments.

10 CHAIRMAN MALMUD: There are two more
11 comments, yes. One from the public?

12 DR. BROGA: I would like to recommend that
13 we go back to using the term that the NRC had used
14 before. And that was "alternate RSO." And the
15 implication at the time was that that person would be
16 credentialed the same as an RSO, would have the same
17 level of authority from the management to serve in the
18 RSO's absence and would be a fully qualified RSO if
19 there were a transfer. And it seems less than an
20 associate and a chief and all of those things. And it
21 had been in play for years.

22 "Alternate" implies that they are equally
23 qualified as the RSO in my opinion. And I would be
24 happy to write that down if anybody would like that in
25 policy.

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1 CHAIRMAN MALMUD: There was another
2 comment. Dr. Zelac?

3 DR. ZELAC: No. I have covered it.

4 CHAIRMAN MALMUD: All right. So the
5 suggestion --

6 MEMBER GILLEY: I am muddying the waters
7 again, but I would like to encourage agreement state
8 participation in this thing so that we have
9 consistency from agreement states and NRC states.

10 MEMBER VAN DECKER: Would you like
11 compatibility B?

12 (Laughter.)

13 CHAIRMAN MALMUD: Dr. Williamson?

14 MEMBER WILLIAMSON: I would propose that
15 Ralph be appointed as the representative of ACMUI to
16 this working group on the RIS.

17 (Laughter.)

18 MS. WASTLER: First of all, it wouldn't be
19 a working group, but --

20 MEMBER WILLIAMSON: Whatever it is.

21 MS. WASTLER: -- we can definitely -- I
22 mean, part of the process would be to bring that, we
23 could very easily bring that, and provide it to the
24 Committee as well as the agreement states to review
25 and comment on.

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1 MEMBER WILLIAMSON: I think I would also
2 suggest to hold off on micromanaging the name of this
3 individual and give the people who put the proposal
4 together opportunity to come back with a more detailed
5 proposal. I think the intent of the motion is clear.

6 CHAIRMAN MALMUD: Dr. Zelac?

7 DR. ZELAC: I changed my mind. I actually
8 do have something to say on this. I think that while
9 the intent is laudable, the practicability is that we
10 will not have this occur without a rule change.

11 The rule as it states now says "a
12 radiation safety officer," one person, period. Now,
13 if there are going to be multiple people, the rule is
14 going to have to be changed in some way.

15 MEMBER LIETO: I think the adjective is
16 also the same in front of an AU, an authorized nuclear
17 pharmacist, and an AMP. So I think if you -- well,
18 again, I would go back to --

19 MS. WASTLER: We'll have to go to OGC.

20 MEMBER LIETO: -- OGC, but I think if you
21 are going to take the adjective and use that to direct
22 a policy, we are going to be micromanaging until the
23 cows come home. And I don't think that's the intent.
24 And reading that rule fully, I did not get that
25 interpretation myself.

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1 MS. WASTLER: We can't speak for OGC here,
2 but I think, suffice it to say, we need to look at it
3 and prepare something and then put it to OGC to see if
4 we could achieve the result that we want given the
5 regulations and the statement of consideration and all
6 the documents supporting that regulation, whether we
7 can manage that that you desire given that, the
8 information as it is written in those documents.

9 So we can go forward. Can we guarantee
10 that OGC once we put this together is going to buy off
11 as we planned? Maybe not. We can't guarantee that.
12 But we will definitely be in contact with the
13 Committee on how this proceeds. And when and if there
14 are stumbling blocks, you will be made aware of them.

15 CHAIRMAN MALMUD: Dr. Suleiman?

16 MEMBER SULEIMAN: I just want to say this
17 so that it goes down on the record. I agree with what
18 Ralph said. I think "a RSO" could clearly be
19 delineated in policy as the RSO who is in charge. And
20 all the other secondary or adjunct or alternate or
21 associate or whatever category you want to call those
22 other additional RSOs would clearly not be the RSO.
23 So I think there's room here to interpret.

24 MS. WASTLER: That's what I tried to
25 portray in terms of what the statement of

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1 consideration and some of the supporting documents to
2 the regs might say. And that may give us the room or
3 the ability to do something along these lines without
4 a rule change because if the intent was to simply make
5 it clear that there is one individual who has the
6 ultimate authority, then maybe that is sufficient for
7 OGC. And what we're doing is not violating that.

8 Basically the bottom line is we have to
9 take it back through our office of legal counsel and
10 see where we end up.

11 MEMBER NAG: We still have a motion on the
12 table that has not yet been voted on.

13 CHAIRMAN MALMUD: All in favor of the
14 motion.

15 (Whereupon, there was a show of hands.)

16 CHAIRMAN MALMUD: Any abstentions?

17 (No response.)

18 CHAIRMAN MALMUD: Any opposition?

19 (No response.)

20 CHAIRMAN MALMUD: It's unanimous. Thank
21 you.

22 MEMBER LIETO: Just one final comment. I
23 am going to be working on this with staff, with
24 agreement states. I think also Dr. Vetter should be
25 involved as the RSO.

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1 CHAIRMAN MALMUD: By all means.

2 MS. WASTLER: We'll make sure that that
3 goes through.

4 CHAIRMAN MALMUD: Thank you.

5 We now move on to the next item on the
6 agenda, which is discussion of the microspheres.

7 11. Y-90 MICROSPHERES GUIDANCE

8 MS. TULL: Cindy is giving handouts right
9 now. It is my presentation and also -- the
10 presentation is in the back for anyone who didn't get
11 it. And the revised guidance is also in the back.

12 I am Ashley Tull, as Dr. Malmud said. I
13 am going to talk about the changes to the microspheres
14 guidance. I am going to outline the changes in my
15 slides. We can discuss the issues. And then we are
16 asking for ACMUI input on several of the issues.

17 At the conclusion of the meeting, the NRC
18 staff path forward will be to take this to the Office
19 of General Counsel to get a no legal objection.

20 And then we will publish the guidance to
21 the Web. And then we're also open to pursue
22 additional discussions, either teleconference or maybe
23 at the next meeting if we still have things that we
24 need to talk about.

25 I would like to note that this is

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1 guidance. These aren't regulations. So even though
2 this doesn't get published in the Federal Register and
3 doesn't go out for official public comment, it is open
4 for comments basically all of the time.

5 So the first change is based on the ACMUI
6 recommendation at the April 2006 meeting. And they
7 recommended that nuclear medicine physicians be
8 included. So we have revised the guidance to say
9 "Authorized users must meet the training and
10 experience requirements of the specific vendor
11 training in the use of microspheres and the
12 microsphere delivery system as either 10 CFR 35.390 or
13 10 CFR 35.490."

14 So I think we have captured that. Are
15 there any comments or any discussion on this?

16 (No response.)

17 MS. TULL: Everyone is happy. Second
18 change, case work. This was also discussed at the
19 April 2006 meeting. And it reads now "Individuals
20 must have work experience, including at least three
21 cases for each type of Yttrium-90 microspheres for
22 which the individual is seeking authorized user
23 status."

24 The second part is "This work experience
25 must be obtained under the supervision of an AU who is

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1 authorized for this type of microsphere."

2 Any comments or questions on that?

3 CHAIRMAN MALMUD: Dr. Eggli?

4 MEMBER EGGLI: Again, for first-time
5 training at an institution who has not previously done
6 the microspheres, the typical approach is for the
7 vendor to come in and train, rather than an individual
8 to go away and work under the supervision of an AU
9 elsewhere.

10 So how would you deal with the issue of
11 sort of the first person who is getting qualified at
12 an institution, again because that training typically
13 comes from the vendor, rather than from another
14 authorized user?

15 MS. TULL: I'll refer to Ron or
16 Donna-Beth. I believe our approach was there are
17 enough people out there currently using these now that
18 it shouldn't be an issue. Am I correct, Ron or
19 Donna-Beth?

20 MEMBER EGGLI: That's an issue.

21 DR. ZELAC: It is an issue, but it depends
22 on where the microspheres are coming from. My
23 understanding is that at least one of the vendors has
24 set up to have the training provided to new users at
25 the facility of an existing licensed user.

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1 And on that basis, there will be an
2 authorized individual at that facility who could
3 assume and document responsibility for the training
4 being provided under the supervision of an authorized
5 user, even though the principal portion of it would be
6 coming from the manufacturer.

7 It may not apply to all microsphere
8 providers but at least the one that I'm aware of.

9 CHAIRMAN MALMUD: Dr. Thomadsen?

10 MEMBER THOMADSEN: We have used both of
11 them. And in both cases, the manufacturer has sent an
12 authorized user to our facility for training was the
13 three required cases.

14 CHAIRMAN MALMUD: Do I understand you to
15 mean that the manufacturer contracted with an already
16 approved --

17 MEMBER THOMADSEN: That's correct.

18 CHAIRMAN MALMUD: -- authorized user to
19 come visit and show?

20 MEMBER THOMADSEN: That is correct.

21 MS. TULL: So, then, this wouldn't be an
22 issue in that case.

23 MEMBER THOMADSEN: That is correct.

24 MEMBER NAG: Now, on this thing, do we
25 need to have the word "authorized user"? "Under the

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1 supervision of someone who is authorized" would mean
2 that person could be the vendor, that person could be
3 an authorized user at another institution.

4 MS. TULL: I think we intended to say AU.

5 MEMBER NAG: Okay. And the second
6 question there is, you know, for example, high-dose
7 rate. There are at least two, but there are more
8 manufacturers having high-dose rate. We don't get a
9 separate license from one or the other.

10 I mean, we are trained in them. And if we
11 go to anything using that has a different machine, we
12 get some training from the vendor, but we don't
13 necessarily put that in the license.

14 So I'm wondering if someone has used the
15 Sirtex, he goes to another institution and goes for
16 the TheraSphere, most of the trainings are similar.
17 Do you need again to do any of the certifications or
18 just have the vendor show you what the differences
19 are?

20 MS. TULL: I'm going to go to Ron and
21 Donna-Beth again. There are differences from last
22 time.

23 MEMBER LIETO: Yes to Dr. Nag. Yes,
24 because they are classified as brachytherapy devices
25 under 1,000. So they're both considered different

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1 brachytherapy devices. So you would need to get the
2 cases for each one.

3 MEMBER NAG: What I'm suggesting is that
4 they are similar. You have experience in one.
5 Otherwise you can have for high-dose rate the
6 high-dose rate machine made by Varian has some
7 differences from the high-dose rate machine made by
8 Gamma-Med and Nucleton.

9 Well, if you have done high-dose rate, you
10 are now licensed for high-dose rate. But now you did
11 that with Varian. So now you have to get a separate
12 license because you are now going with Nucleton.

13 So I would suggest that -- this is my
14 suggestion -- we say if you have three cases of
15 yttrium-90 microsphere and not relate that to which
16 manufacturer.

17 CHAIRMAN MALMUD: Dr. Thomadsen?

18 MEMBER THOMADSEN: Perhaps Dr. Welsh would
19 expand on this more, but medically the two devices are
20 not similar. And mechanically they are not similar.
21 And the training on one modality is not directly
22 applicable to the other.

23 CHAIRMAN MALMUD: Dr. Welsh?

24 MEMBER WELSH: I would agree with what Dr.
25 Thomadsen just said, but I also agree with Dr. Nag's

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1 point in general terms. Three cases for Sirtex, for
2 example, is necessary, sufficient.

3 But then if somebody who has had dozens of
4 cases of using SIR-Spheres wants to learn
5 TheraSpheres, do we need three cases of that? Perhaps
6 just one or two examples with the vendor training and
7 certification would suffice in that context.

8 MEMBER NAG: Yes. I mean --

9 MEMBER WELSH: As written now, it says at
10 least three cases for each type.

11 MEMBER NAG: Right. I mean, you know,
12 it's a similar example I'm giving to the high-dose
13 rate machine. Each high-dose rate machine is entirely
14 different. They have many different nuances. And
15 when you change from one to the other, you do get some
16 vendor training, but that is not written into the
17 license.

18 My objection is writing it into the
19 license. I'm not objecting to having vendor training
20 when you shift from one manufacturer to the other.

21 CHAIRMAN MALMUD: I think the next person
22 was a member of the public.

23 MS. WARBICK: Hello. I'm Ann Warbick from
24 MDS Nordion. I would like to explain to you from a
25 very practical perspective what actually is working

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1 today.

2 MDS Nordion has established centers of
3 excellence in the various jurisdictions throughout the
4 world. In the United States, we have a center of
5 excellence which I guess we would have what's called
6 a preceptor at that center of excellence who provides
7 training to all new users. And I mean all new users.

8 So all new users will go to that site.
9 And at that site, they will receive didactic and very
10 practical training where patients are actually being
11 set up on the day of their visit to be treated. There
12 will probably be two to three patients treated on that
13 particular day.

14 And then following that, the physician who
15 is going to become an authorized user of TheraSphere
16 goes back to this site. And he is then proctored for
17 the first three administrations. And he works very
18 closely with the preceptor on these administrations.

19 Though the preceptor may not necessarily
20 be present at the time when the administrations are
21 taking place, there is a proctor present at the site
22 at the time of the first three administrations. If
23 the site needs more than three, they can have more
24 than three preceptored administrations.

25 One of the issues that I would like to

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1 bring up is we have discussed this guidance with our
2 preceptor. And he has some concerns about the use of
3 the word "competency." And the use of the word
4 "competency" is discussed in paragraph number 4. And
5 that's a term that was brought up yesterday as well.

6 MS. TULL: I will be covering that in my
7 presentation if you want to wait. It will be the next
8 slide.

9 MS. WARBICK: Okay. Thank you.

10 CHAIRMAN MALMUD: Dr. Williamson?

11 MEMBER WILLIAMSON: Well, I think the
12 vendors can recommend or require what they want, but,
13 you know, in the end, I really wonder if Dr. Nag
14 doesn't have a very good point here.

15 When 390 authorization is given to a
16 physician, they are not expected to do three cases for
17 all of the dozens of radiopharmaceutical products that
18 are available. They are expected to show 12 cases
19 distributed among 4 different modalities as a kind of
20 a baseline minimum to document their competence.

21 And I'm wondering if this class of devices
22 shouldn't be treated the same way, at least. From a
23 regulatory point of view in the community, one, of
24 course, can have more rigorous training standards.

25 CHAIRMAN MALMUD: Dr. Suleiman?

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1 MEMBER SULEIMAN: I have a question. How
2 accurate is the activity that's administered? And
3 could any of the manufacturers maybe address that?
4 Because I think dosimetry is one of the fundamental
5 issues in using this technology.

6 MS. TULL: Dr. Malmud, that is an issue in
7 my presentation as well. If you guys want to wait to
8 get to that, there's a slide on it.

9 CHAIRMAN MALMUD: Go ahead. Mr. Lieto?

10 MEMBER LIETO: It seems like the
11 presentation just given by MDS Nordion, there are
12 actually six cases, three of which meet this
13 requirement. I guess you have work experience versus
14 proctoring. I don't know if we want to make any
15 distinction between that, but it would seem like what
16 they're doing now more than meets what we're asking
17 for anyhow.

18 I would hate to reduce the number of
19 cases. And my reasoning is such that currently there
20 have been several medical events over the past few
21 years involving this modality. And I don't think it
22 would be prudent to reduce the number of cases below
23 I think these three if it's especially something
24 that's being done already by the vendors.

25 MS. TULL: This is something that I took

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1 directly from the transcript at the last ACMUI, not
2 the last one but the April 2006 ACMUI meeting. This
3 was discussed in detail, 60-something pages of this.
4 And so this is coming directly from your discussions,
5 just for new members and --

6 MEMBER LIETO: We're not allowed to change
7 our minds?

8 (Laughter.)

9 MS. TULL: You are allowed to do anything
10 you want to do. I mean, I literally went through the
11 transcript and pulled out action item, action item,
12 and my slides are based on basically your
13 recommendations from that meeting.

14 CHAIRMAN MALMUD: Dr. Nag?

15 MEMBER NAG: Again, I am not trying to cut
16 down the number of things that you need to do. What
17 I am trying to say is that if you have experience in
18 one modality, if you have done 1,000 cases of
19 manufacturer A's, you know that there are some
20 differences between the two spheres. So you multiply
21 your insertion in that way.

22 You do not need any identification because
23 then if you have this, you are going to translate that
24 to other modalities. And the example I gave you was
25 690, where there's a difference between a Gamma-Med

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1 high-dose rate and a difference between Varian
2 high-dose rate.

3 And, again, you know, if you have done
4 1,000 cases there, you do need some vendor and stocks
5 who knows the differences but not the licensing
6 requirement. And what I'm against is the licensing
7 requirement when you already have experience in one
8 and you are licensed in one to go through any of the
9 -- it's not a different modality. It's the same
10 modality.

11 So I'm trying to make that distinction
12 between someone who has no experience in the modality
13 but with someone who is well-experienced in the
14 modality using one manufacturer's microsphere versus
15 the other manufacturer's microsphere.

16 CHAIRMAN MALMUD: Okay. Dr Nag, how does
17 that resolve with Dr. Thomadsen's point that sometimes
18 the two different modalities are quite different?

19 MEMBER NAG: They are different. The
20 microspheres are different. I led the consensus panel
21 that gave the guidelines for using microspheres. And
22 in that document, we made very clear the differences
23 between the two.

24 Similarly, I mean, when I have a license
25 for iodine-125 used for manual brachytherapy under

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1 490, they are entirely different. I don't need a
2 separate license now to go in and do iridium. And if
3 I had to do that for 490, I would require three cases
4 of iridium, three cases of iodine, three cases of
5 whatever new isotope is coming in. They are entirely
6 different isotopes, here the same isotope.

7 Here they are all encapsulated. One is
8 heavier than the other. One has a larger size than
9 the other. There are minute differences. But the
10 entire concept is still the same.

11 PARTICIPANT: I don't think we are
12 requiring an additional license, are we?

13 CHAIRMAN MALMUD: Dr. Welsh, yes?

14 MEMBER WELSH: I agree with what Dr. Nag
15 is saying again in general, but the way it is worded
16 now is such that it's automatically taken care of with
17 the vendor training. The vendor training is going to
18 provide at least three, typically six from both of the
19 FDA-approved devices. And from a practical
20 perspective, it's already met.

21 MEMBER NAG: Well, 490 if you're not
22 approved, you do iodine-125 implants. When you go to
23 iridium, it's an entirely different isotope, entirely
24 different technique. You are going to have another
25 reapplication for a license because that is exactly

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1 the same similarity. In fact, there is more
2 similarity in between TheraSphere and Sirtex
3 Yttrium-90 than between iridium-192 and permanent 125
4 implant.

5 I am just trying to make the rationale.
6 If you are trying to make the rationale there is some
7 minute differences between TheraSpheres and Sirtex, my
8 contention is that might make a difference between
9 each of these up to 490.

10 CHAIRMAN MALMUD: Thank you.

11 Dr. Zelac?

12 DR. ZELAC: I should note, Dr. Nag, that
13 for 490, there is no specific training requirement.
14 It's only for 690.

15 MEMBER NAG: Well, even for 690, the
16 differences between Gamma-Med, between Varian, and
17 between Nucletron, under the sources cited, there are
18 lots of differences. The training, the way you do the
19 treatment planning exam was different, too.

20 DR. ZELAC: If I can add one more word,
21 this question of whether the type of use was
22 device-specific or not was brought to NRC counsel for
23 an interpretation. My recollection is that it was not
24 to be specific to the particular device but just to
25 the type of device; HDR, for example. But I'm not

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1 sure, and we'll have to check.

2 CHAIRMAN MALMUD: Thank you.

3 DR. ZELAC: I am not sure what the
4 interpretation was from OGC. I was of a differing
5 opinion.

6 CHAIRMAN MALMUD: Did you mean the Office
7 of General Counsel?

8 DR. ZELAC: Yes.

9 CHAIRMAN MALMUD: Comments from the
10 public?

11 MR. PFEIFFER: Doug Pfeiffer. You made a
12 comment about citing the fact that the manufacturers
13 are currently providing training that meets these
14 requirements.

15 I think it's dangerous to form a
16 regulation around what a manufacturer is currently
17 providing, that if the manufacturer would decide to
18 change what they're doing and may become a burden to
19 try to meet what that requirement is, that they should
20 be fashioned around what is truly required.

21 And if the manufacturer can help do that,
22 that's great. But don't make it dependent upon what
23 the manufacturer is doing in case they would change it
24 in the future.

25 MS. TULL: I would like to note this is

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1 guidance. So it's not going to be the same as
2 regulation. It's a 1,000-use. So if we found out, if
3 we were notified that the manufacturers changed their
4 procedures and that, all of a sudden, users couldn't
5 get approved because they couldn't get these three
6 cases, again, we would come back and revise the
7 guidance. It's much more easily done than rulemaking.
8 This isn't in a regulation yet.

9 CHAIRMAN MALMUD: Mr. Lieto?

10 MEMBER LIETO: Yes. I just want to go
11 back to Dr. Nag's point about doing it by isotope. As
12 Dr. Thomadsen pointed out, looking at the radiation
13 safety considerations, not the isotope, these are two
14 distinct performing types of devices and
15 radiopharmaceuticals. And they have distinct
16 differences that affect the radiation safety
17 characteristics.

18 And so I think as long as they are going
19 to be under 1000, they don't want to put them under
20 390 as a non-sealed radiopharmaceutical and they are
21 going to be considered a device with these
22 distinctions, then I think that the number of cases.

23 And, as it says, for each type of -- to
24 address Dr. Zelac's point, it says for each type of
25 microsphere. So it would apply to both different

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1 vendors as currently written.

2 And, to support Ashley's point, that's
3 what we did agree upon at the last meeting, when we
4 discussed this.

5 CHAIRMAN MALMUD: Thank you.

6 Let's see. Dr. Thomadsen?

7 MEMBER THOMADSEN: Well, I'll reflect back
8 to Dr. Eggli that I may be allowed to change my mind
9 and that I think good points have been made that if
10 you do have experiences with one, even though there
11 are differences, maybe you don't need the three
12 proctored examples with the other.

13 I'm not sure of what the number would be.
14 And the difference between three and one is not that
15 great. And it may be more complicated to try to craft
16 this to allow previous experience with one to reflect
17 the other or any others that come into the field, but
18 I wouldn't be dogmatic, as it sounded at first.

19 CHAIRMAN MALMUD: Dr. Williamson?

20 MEMBER WILLIAMSON: Well, I think that the
21 way this is written, it really kind of micromanages by
22 saying who has to supply the training. It requires an
23 authorized user to be flown in. This is going to add
24 to the expense of the ultimate procedure.

25 And I think, you know, if you're making

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1 the case that this is important, Ralph, you need to
2 justify it on grounds of health and safety. So I
3 would say make it more generic, that there should be
4 a minimum case experience of three cases with products
5 of this type and for additional models or forms,
6 similar forms, of the same product.

7 Users should be expected to follow
8 vendors' recommended training and leave it at that so
9 that there is some flexibility to tailor this to the
10 differing levels of expertise so that cost of health
11 care might be appropriately minimized.

12 CHAIRMAN MALMUD: May I ask a question of
13 NRC staff? Has there been any reported event thus far
14 of a case in which there was a new technology being
15 employed and in which there was an error occurring
16 because the individual was new to the procedure?

17 DR. HOWE: Yes. And for the microspheres,
18 when they were first introduced, the first three cases
19 were medical events. And in the last three or four
20 months, we have had four medical events with the
21 microspheres. And that's based on the delivery.

22 MEMBER NAG: I think your question was
23 slightly different. Your question, I believe, was
24 that someone who has already been experienced in one
25 kind of microsphere went into a different kind of

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1 microsphere. And then did it result in a medical
2 event? Am I right?

3 I mean, there are problems. There are
4 misadministrations with microspheres in general. We
5 know about that. But that is not because of one
6 strange individual going from one system to the other.

7 CHAIRMAN MALMUD: That wasn't my question.
8 My question was, in the application of new techniques,
9 have there been reported events?

10 MEMBER NAG: Of course.

11 CHAIRMAN MALMUD: Because I am thinking
12 now from the standpoint of a patient. If I were a
13 patient in an institution of great reputation and I
14 was told that I was going to be the first patient to
15 have this new technique applied, I would want to have
16 confidence that the people who were doing this had
17 been trained in doing it, even though they had vast
18 experience in other areas.

19 And my question is, has there been an
20 incident or have there been incidents in which this
21 new technology is being applied by people who are not
22 trained in that specific new technology and, as a
23 result, errors occurred?

24 I think, Dr. Zelac, you had your hand up?

25 DR. HOWE: And the answer is definitely

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1 yes. The answer is definitely yes. And the answer is
2 definitely yes for this particular type of --

3 CHAIRMAN MALMUD: So if the answer is
4 definitely yes and definitely yes, then it's
5 definitely of concern for the public's interest that
6 there be supervision, meaning experience on the part
7 of the individual who is introducing this new
8 technique at his or her own institution.

9 Did that cover your point, Dr. Zelac, or
10 are you going to make another one?

11 DR. ZELAC: Just to make it even clearer,
12 anecdotally there was a case recently where a medical
13 event did occur because the stop-cock was turned the
14 wrong way. The material, instead of flowing into the
15 patient, flowed into a waste reservoir.

16 MEMBER NAG: Yes, but --

17 CHAIRMAN MALMUD: Was this a new
18 application?

19 DR. HOWE: I believe that was an
20 experienced site, but I'm not sure.

21 MEMBER NAG: I think --

22 DR. HOWE: We have had them for the new
23 applications because it --

24 MEMBER NAG: No. There's a difference in
25 new applications and someone already experienced in

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1 one microsphere shifting to the other microsphere.
2 You are probably talking about someone who is doing
3 the

4 If someone doesn't know anything

5 DR. HOWE: I believe we have had medical
6 events in both cases. I would have to go back and
7 check.

8 CHAIRMAN MALMUD: Dr. Eggli?

9 MEMBER EGGLI: I think that, again, I
10 would like to come back to the under the supervision
11 of an authorized user. These events if they are going
12 to occur, the question is, are they any less likely to
13 occur because an authorized user is standing there, as
14 opposed to an expert provided by the vendor who knows
15 their system inside out and the training and is
16 providing the training for the use of the device?

17 My concern is under the supervision of an
18 authorized user. I will agree that vendors are
19 currently providing an authorized user, but, again,
20 that may not permanently be the case. I seriously
21 doubt that the presence of an authorized user provides
22 any level of safety above and beyond the other
23 expertise that the vendor can provide during training
24 and that public safety is not enhanced by having an AU
25 stand there, as opposed to the representatives of the

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1 vendor. And it certainly adds cost to the process and
2 may limit entry of practitioners.

3 DR. HOWE: Dr. Malmud, can I make a point?

4 CHAIRMAN MALMUD: Yes, please.

5 DR. HOWE: The ACMUI seems to be focusing
6 on when the device comes into a facility for the first
7 time. This guidance is also used to train additional
8 users at an established location. So this would be --

9 MEMBER EGGLI: But that doesn't change the
10 rule for the new user. I mean, your impact --

11 DR. HOWE: This is for any user.

12 MEMBER EGGLI: I understand the training
13 of subsequence. But if you're going to train, when
14 the device comes in for the first time, this is an
15 impact as the devices come in the first time and I
16 think an unnecessary impact.

17 CHAIRMAN MALMUD: Let me, if I may, just
18 explain why I asked the question. I asked the
19 question because it is of concern to me that a
20 technique being used by someone who has not had
21 experience before puts the patient at risk.

22 So that in looking at the statement
23 currently on the slide, it seems to me that that risk
24 to the patient could be covered by changing the second
25 quotation, which begins "The work experience must be

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1 obtained under the supervision of an experienced
2 user."

3 And that experienced user could be a
4 physician. It could be someone from the manufacturer
5 but someone with experience. Otherwise it's the
6 unknown. It's the inexperienced supervising the
7 inexperienced. Even though the person may be an
8 authorized user, that person may not be an experienced
9 authorized user in the technique being employed. What
10 we are seeking is someone who has done this before.

11 I don't know that the authorized user
12 satisfies that, and I certainly would not put into
13 regulation something that depends upon the vendor but
14 simply identifying under the supervision of an
15 experienced user.

16 Does that seem reasonable? Dr. Zelac?

17 DR. ZELAC: If you continue on to the
18 remainder of the quotation, it does limit that
19 authorized user to be one who has experience in the
20 use of those particular products.

21 CHAIRMAN MALMUD: Yes. Well, of the
22 particular technique for which the individual was
23 seeking approval.

24 DR. ZELAC: Right. So it removes, I
25 think, the concern that you had about somebody being

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1 an AU and not really knowing what they're doing but,
2 yet, supervising the training of someone else.

3 DR. ZELAC: Oh, I wasn't suggesting that
4 the AU didn't know what the AU was doing. I was
5 suggesting that the AU might not have had experience
6 in that particular microsphere if there is this
7 generic argument about the microspheres.

8 I just think if I were a patient, I would
9 want to know that if I am going to be the first
10 patient to have this technique applied to me at this
11 outstanding institution, that someone is there who has
12 done this before. That's the assurance that I want as
13 a patient.

14 Now, it may be that person may make an
15 error, but that person is less likely to make an error
16 that someone who has never done it before. And that's
17 what concerns me from our role in protecting the
18 public.

19 I'm sorry. Dr. Williamson?

20 MEMBER WILLIAMSON: I think we could argue
21 and argue what should be the minimum level of
22 training. I think in other cases, like gamma knife
23 and high-dose rate brachytherapy, rather than try to
24 solve the dilemma of what the minimum content of
25 device-specific training is, we basically say it's

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1 what the vendor recommends.

2 So user should undergo the minimum
3 training, as recommended by the vendor for a new user,
4 period. And if the vendor's protocol allows for the
5 internal transmission of knowledge from an in-house
6 experienced authorized user to another, so be it.

7 If the vendor requires a trained technical
8 representative from their company to come whenever a
9 new authorized user is added to the license, so be it.
10 But that way we don't have to micromanage it. And we
11 could handle it the same way high-dose rate and gamma
12 knife training is handled.

13 MS. TULL: Dr. Malmud?

14 CHAIRMAN MALMUD: I'm sorry. So are you
15 supportive of the statement as it appears in --

16 MEMBER WILLIAMSON: No, I am not.

17 CHAIRMAN MALMUD: You're not. Okay.

18 Dr. Nag?

19 MEMBER NAG: I think, again, you make the
20 right point that as a patient, you don't want to be
21 the first one, and you want to have someone who has
22 been supervised.

23 My objection is if you have been
24 experienced in one kind of microsphere, most of the
25 things are similar. There are certain individual

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1 differences. You know, the procedure is being done by
2 someone who is experienced in microsphere, but the
3 manufacturer of the microsphere is different.

4 So I don't think you need to be
5 reproctored by -- well, another certification just
6 because you are changing the microsphere because if
7 you are going to do that, you have to do that for
8 every other thing.

9 Any time you change from Strontium to some
10 other thing or from -- they are entirely different
11 things. I mean, the decay for iodine is different
12 from the decay point for iridium. So if you know
13 iodine and you have done 1,000 iodine implants, you're
14 going to iridium, you need to have another license all
15 over again.

16 CHAIRMAN MALMUD: Thank you.

17 DR. HOWE: If I could just make an
18 interjection? I don't really want to expand this, but
19 Dr. Nag's point is, say, for manual brachytherapy or
20 for HDR.

21 And in those, the training and experience
22 that is required is three years of clinical
23 experience. And in that three years of clinical
24 experience, there is an assumption that you will see
25 a variety of things in your training and experience.

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1 And so you will have already been subjected to a
2 variety of things, a variety of isotopes, a variety of
3 procedures. This is an emerging technology, a new
4 technology.

5 People have not been exposed to a variety
6 of these. We're in the beginning stages. There are
7 significant differences in the delivery of the
8 TheraSpheres versus the SIR-Spheres. And you just
9 cannot go from one to the other without really truly
10 comprehending those differences and the mechanics of
11 those differences. And that's why we put in that it
12 would be the microsphere-specific training and the
13 experience to try to eliminate the problems of going
14 from one to the other and having problems. One
15 floats. One doesn't.

16 CHAIRMAN MALMUD: We have a comment from
17 the public.

18 MR. THURSTON: Good morning. My name is
19 Ken Thurston. I represent Sirtex Medical, but I have
20 also had extensive experience with TheraSphere. In
21 fact, I was responsible for starting the clinical
22 development of this device in 2000.

23 And to your point about inexperienced
24 users, when we went to treat the first patient because
25 the technology had been somewhat dormant for about ten

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1 years, we had a medical event. And there was
2 contamination of the laboratory as a result of a
3 technical issue.

4 And, as a result, MDS already went through
5 some extensive revisions to the product. And this is
6 the nature of new product development and new
7 technology development.

8 I think that both manufacturers in the
9 last -- and then, of course, SIR-Spheres were
10 introduced in 2002. In the last six or seven years,
11 both manufacturers have gained considerable experience
12 and have done a much, much better job of training and
13 specifying site qualification and checklists and
14 procedures. And both manufacturers do a very, very
15 diligent job of that endeavor.

16 Having said that, as people have pointed
17 out, medical events will occur with any new
18 technology, with any new user. And I think that all
19 of that needs to be taken into context here in terms
20 of this regulation because the other thing that is
21 happening is that there are other Y-90 brachytherapy
22 devices that will be coming into the fore as patents
23 run out and as the technology expands.

24 So I think that there needs to be a
25 balance between ensuring safety in terms of radiation

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1 safety procedure, safety to the patient, and coming up
2 with regulations that everybody can live with.

3 And I think Dr. Williamson's suggestion
4 about generic training, from a medical and safety
5 perspective, and then provisions as additional devices
6 come on board or additional manufacturers come on
7 board is probably a good one.

8 Thank you.

9 CHAIRMAN MALMUD: Thank you.

10 Another member of the public?

11 MS. FAIROBENT: Yes. Lynne Fairobent. I
12 have a slightly different twist on this. And part of
13 it goes back to Ashley's comment of this being
14 guidance.

15 Yes, while it's true this on the face of
16 it is guidance because this is a Part 1000 regulation,
17 we are actually regulating by guidance. And, in fact,
18 if you look at your draft regulation, this requires a
19 license amendment by existing individuals to adopt a
20 new guidance before they can continue. So we are
21 regulating by guidance.

22 When Part 1000 was originally conceived,
23 it was with the intent that it would not stay in Part
24 1000 forever. We now have between five and seven
25 years.

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1 My question comes down to, when are we
2 going to develop and put this into one of the existing
3 parts of the regulation, take it out of Part 1000, and
4 truly put this out for public review and comment?

5 I applaud NRC for working with the vendors
6 to help develop this guidance, but to my knowledge,
7 this has not been distributed or asked for any public
8 input. Perhaps that's coming down the pike, but in
9 the past, the guidance has simply appeared on the Web
10 site without formal notice for public comment.

11 I just raise the question because this is
12 another example of seven years down the road under
13 Part 1000 implementation. And it was never intended
14 for emerging modalities to live in Part 1000 forever.
15 We have never defined what the appropriate length of
16 time is for moving something out of Part 1000, but we
17 continue to regulate by license amendment.

18 MS. TULL: To address part of your
19 question, guidance, you're correct, does not go out
20 for public comment. That is not the current NRC
21 practice. That's not how guidance is done.

22 For rulemaking, I will have to ask Ron or
23 Donna. Do we have anyone from DLR here for
24 rulemaking?

25 MS. WASTLER: With regards to?

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1 MS. TULL: How long it takes to go from
2 guidance to --

3 MS. WASTLER: Well, part of the problem I
4 think is, one, being new modality. When you move
5 something into regulatory space, you want to make sure
6 that what you have set forth is appropriate.

7 In other words, you know, it is a new
8 modality. Things change. Problems occur. What you
9 start out with -- I think this is the thought process
10 behind the 1000, is that as you move through these,
11 you know, initial stages, what you conceptually
12 thought might work as you move through it, you know,
13 after the first case versus the third versus the
14 fifth, that things change.

15 And so putting something in 1000 allows us
16 -- because it's technically draft guidance, it's out
17 there. And anyone can comment on it. Anyone can
18 point out the changes. And we can go in and say,
19 "Okay." Based on, say, comments from ACMUI, we can go
20 back and say, "This isn't working." And then we can
21 put another version on it.

22 I agree with Lynne. Some of these have
23 been on for a long time, which in some cases is a
24 result of budget. You know, I mean, it's not a
25 necessarily satisfactory answer, but it is the reality

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1 of the situation that when you go to rulemaking, it is
2 an extensive process. It is a costly process.

3 Being the fact that we do accept any
4 comments at any time on it, you know, from anyone, you
5 know, I think we're trying to meet our obligation of
6 being responsive to any problems that come out of it.

7 MS. TULL: Which is why my name is on the
8 Web site now.

9 (Laughter.)

10 MS. WASTLER: Now I can point to her.

11 CHAIRMAN MALMUD: Dr. Welsh and Dr.
12 Suleiman. Dr. Welsh?

13 MEMBER WELSH: Going back to what is
14 written there, it says, "at least three cases."
15 Question mark. But should it really be there in the
16 license requirements?

17 Right now the vendors provide at least
18 three, six cases in most situations. So I feel that
19 that is being met. And I am comfortable with it
20 saying "at least three cases" because I know that we
21 are always getting at least three, typically much
22 more.

23 As was pointed out by a member of the
24 public, what if the vendors decided one case is all we
25 are going to pay for? Well, this takes care of that.

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1 That way it answers Dr. Malmud's point about whether
2 an authorized user has experience with this apparatus
3 if that patient is one of the early individuals coming
4 to this institution to get this.

5 As I look at paragraph number 2, it seems
6 that the authorized user is experienced by paragraph
7 number 1. And, therefore, paragraph number 2 is okay
8 since an authorized user based on paragraph number 2
9 is somebody who has experience from paragraph 1. And,
10 therefore, I think it's fine the way it's written.

11 MEMBER EGGLI: Except that authorized user
12 is a special category recognized on an NRC license.

13 CHAIRMAN MALMUD: That was Dr. Eggli
14 saying that "Except that authorized user is a special
15 category recognized on a license."

16 MEMBER WELSH: And somebody with
17 specialized training and at least three cases of
18 documented experience.

19 CHAIRMAN MALMUD: Dr. Suleiman?

20 MEMBER SULEIMAN: All right. I am not
21 sure when I wanted to interject this, but I think it
22 would help a little bit. I think there are radiation
23 safety issues here clearly, which I think is the role
24 of the Advisory Committee.

25 I would like to clarify the specific

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1 indications for which these two products were approved
2 by FDA just to remind people that we are dealing with
3 a very specific application.

4 The TheraSpheres were approved with a
5 humanitarian device requirement saying -- I'm just
6 reading from the label -- "Authorized by federal law
7 for use in the radiation treatment or as a neoadjuvant
8 to surgery or transplantation with patients with
9 unresectable hepatocellular carcinoma who can have
10 placement of appropriately positioned hepatic arterial
11 catheters. The effectiveness of this device for this
12 has not been demonstrated."

13 The indication for TheraSpheres -- excuse
14 me. That was the warning. The indication for
15 TheraSpheres is "TheraSphere is indicated for
16 radiation treatment or as a neoadjuvant to surgery or
17 transportation in patients with unresectable
18 hepatocellular carcinoma who can have placement of
19 appropriately positioned hepatic arterial catheters."

20 The indication for the SIR-Spheres is
21 "SIR-Spheres is indicated for the treatment of
22 unresectable metastatic liver tumors from primary
23 colorectal cancer with adjuvant intrahepatic artery
24 chemotherapy."

25 So we're dealing with very, very specific

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1 approvals. And also obviously these can be used under
2 the practice of medicine based on the experience of
3 the physician.

4 So we're dealing with clearly a new, very,
5 very new, modality with some real risks. But are the
6 issues radiation safety? Are the issues practice of
7 medicine?

8 I mean, there are some gray areas here.
9 We are dealing with a very vulnerable population, you
10 know, very, very unique patient population here.

11 CHAIRMAN MALMUD: The issue for us is the
12 radiation safety.

13 MEMBER SULEIMAN: Right.

14 MS. TULL: Dr. Malmud, on that same note,
15 we actually had a teleconference with one of the
16 manufacturers. And when they talked about this, I
17 mean, they stated what it is being used for in the
18 U.S. is not really what the clinical trials were at
19 all. There were 74 cases. And it was used as a
20 first-line treatment.

21 And in the U.S., it is not used that way.
22 It's usually a last resort. So the way it is being
23 implemented in the U.S. is not -- I mean, what they
24 submitted to FDA and how it got approved, under the
25 practice of medicine, it's being used very

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1 differently.

2 CHAIRMAN MALMUD: Dr. Nag?

3 MEMBER NAG: Yes. Again, I wish to
4 clarify or state I am very much, we are very much
5 aware of what the FDA approval was, but that was,
6 what, several years ago. However, the current
7 indications and the current way it's used, it's
8 basically a higher percentage of off-label use, not
9 the way -- because almost everyone is going to be off
10 label because this was with Sirtex. It was with the
11 use of chemotherapy. Now that chemotherapy is no
12 longer used.

13 So I am aware of all of these differences.
14 And what I am trying to say to the rest of the ACMUI
15 and the NRC, we literally spent hours and hours on
16 discussion when we made our recommendation from the
17 panel.

18 And the indication, we get that there was
19 a difference between these two microspheres, but in
20 terms of the medical use, they have been used almost
21 identically.

22 And if you have the training, you know
23 where it is to be used, what the signs are. You know,
24 that is an important part of the training. And that
25 training is the same for both.

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1 So the differences between the two
2 microspheres are something that can be taken care of
3 by vendor training without needing licensing
4 requirements.

5 My objection is putting it into the
6 license, not in the training. I am all for the
7 training.

8 CHAIRMAN MALMUD: Therefore, Dr. Nag, how
9 would you alter this proposal that's on the slide?

10 MEMBER NAG: And I would like to make it
11 in the form of a motion.

12 CHAIRMAN MALMUD: What is your motion?

13 MEMBER NAG: My motion is that the
14 individual must have work experience, including at
15 least three cases of Y-90 microsphere. Take out that
16 word "for each type of." So that's one.

17 Under the second paragraph, the word
18 "experience" might be obtained under the provision of
19 AU. You know, you have to substitute with someone
20 with experience with the microspheres. So then --

21 CHAIRMAN MALMUD: That is your motion?

22 MEMBER NAG: Yes.

23 CHAIRMAN MALMUD: Is there a second to Dr.
24 Nag's motion?

25 MEMBER WILLIAMSON: I would offer a

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1 friendly amendment --

2 MEMBER NAG: Yes. That's fine.

3 MEMBER WILLIAMSON: -- to Dr. Nag's
4 motion. I would in the second paragraph put "under
5 the supervision of a representative that complies with
6 the vendor's training protocol."

7 MEMBER EGGLI: I would second the
8 amendment.

9 MEMBER NAG: I would agree with that.

10 CHAIRMAN MALMUD: There is now a motion
11 which has been amended. Is there any discussion of
12 this motion? Mr. Lieto?

13 MEMBER LIETO: I am very much opposed to
14 those changes. I think this is a minimum requirement
15 based on current vendor practice. We discussed this
16 at 60 pages at length. And, actually, you're probably
17 going to get another 60 pages on it now.

18 (Laughter.)

19 MEMBER LIETO: I think if it were my
20 family member or whoever that was going in this, I
21 would want somebody with not 3 cases but probably 300.
22 But it probably is not going to be the case.

23 You're looking at a use that has medical
24 events. It's a new modality. And I think we're
25 ratcheting it down to basically saying you only need

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1 three cases of any sort without even having an AU
2 present during the training and experience.

3 I think that AU brings not just the
4 radiation safety aspects but also the clinical aspects
5 of training and expertise in these work experience
6 sessions.

7 And most of these people that are starting
8 up in this have never done anything of this nature
9 with unsealed radiopharmaceuticals. And so I think to
10 minimize it below what the vendor is already doing, I
11 would not support.

12 CHAIRMAN MALMUD: Excuse me. So your
13 objection is one which would be overcome by accepting
14 the statement as it is presented?

15 MEMBER LIETO: I would like to keep it
16 just as it was --

17 CHAIRMAN MALMUD: So you are in favor of
18 it as it was presented --

19 MEMBER LIETO: Yes.

20 CHAIRMAN MALMUD: -- versus that which Dr.
21 Nag has proposed?

22 MEMBER LIETO: Yes.

23 CHAIRMAN MALMUD: Dr. Eggli?

24 MEMBER EGGLI: I have to disagree with
25 Ralph on the issue that having an AU standing there

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1 brings much to the table over the vendors' training
2 program. I just have to really strongly disagree with
3 that.

4 I think those of us who are practicing
5 this understand the radiation safety issues. And it's
6 just learning to use the device. And having an AU
7 from another institution stand there doesn't bring
8 anything to the table that the vendor training doesn't
9 bring.

10 I understand your concern about number of
11 cases, but I really object to the AU part of that
12 training requirement.

13 MEMBER LIETO: But no. What you're
14 changing to is that you never even have to have an AU.

15 MEMBER EGGLI: No, that's not. They're
16 saying for the training. This only says work
17 experience must be obtained. That's for the purpose
18 of getting onto the license. You have to be an AU to
19 get onto the license.

20 The second paragraph deals with who
21 provides the training necessary to achieve AU status.

22 MEMBER LIETO: Right.

23 MEMBER EGGLI: I don't think that training
24 needs to be provided by someone who carries an AU. In
25 the other modalities, in higher risk modalities,

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1 high-dose therapies, you don't have to be trained by
2 another AU.

3 You have to be trained by the
4 manufacturer's representative or you have to be
5 trained to the level required by that manufacturer,
6 whatever that manufacturer recommends for the use of
7 equipment at far more risky therapies than this one.

8 The standard is that the vendor determines
9 what the threshold is. Why should the standard for
10 microspheres, which is, in fact, lower risk than
11 high-dose rate therapies, be any different?

12 CHAIRMAN MALMUD: Dr. Welsh?

13 MEMBER WELSH: Perhaps that second
14 paragraph, that first sentence can be modified to say
15 "under the supervision of an experienced AU who is
16 authorized for this type of microsphere for which the
17 individual is seeking approval."

18 At an institution where an authorized user
19 has done a few hundred cases and then another
20 individual comes to that department seeking AU status
21 for this particular microsphere application, why does
22 the vendor have to come and provide 3 cases when the
23 authorized user at that institution might have done
24 300 and be the one that goes to other institutions to
25 --

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1 CHAIRMAN MALMUD: I think you're looking
2 at start-up.

3 MEMBER EGGLI: I was looking at start-up.

4 MEMBER WELSH: But I think this is a
5 general plight here and not exclusively for start-up.

6 CHAIRMAN MALMUD: Dr. Zelac I think was
7 next.

8 DR. ZELAC: I think it might be useful to
9 take a look at the training requirement that exists
10 under 690 and the wording that is included there.
11 Again, this is for the various therapeutic devices,
12 "Has received training in device operation, safety
13 procedures, and clinical use for the types of use for
14 which the authorization is sought. This training
15 requirement may be satisfied by satisfactory
16 completion of a training program provided by the
17 vendor for new users or by receiving training
18 supervised by an authorized user or authorized medical
19 physicist as appropriate who is authorized for the
20 types of use for which the individual is seeking
21 authorization."

22 PARTICIPANT: I like that.

23 PARTICIPANT: I like that, too.

24 MEMBER NAG: I have no problem.

25 MEMBER EGGLI: And that's for higher-risk

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1 therapy. Why should that same training -- you know,
2 if that were applied to microspheres, I would be
3 perfectly satisfied.

4 PARTICIPANT: I agree.

5 MEMBER FISHER: I would agree to that
6 also.

7 CHAIRMAN MALMUD: Dr. Nag, would you
8 agree?

9 MEMBER NAG: Yes, I would agree to that
10 second paragraph. My objection was on that first
11 paragraph, where having experience in one kind of
12 microsphere and now you go and do it again just
13 because you're changing the manufacturer. My
14 objection was not with supervising. I absolutely
15 agree there.

16 I think, again, maybe I can ask my
17 colleague, Mr. Lieto, if you had a relative who was
18 going to undergo this therapy, would you rather do it
19 by someone who has done 1,000 cases of --

20 MEMBER LIETO: Yes.

21 MEMBER NAG: Okay. You said "Yes" already
22 before I finished my sentence. All right.

23 -- 1,000 cases of Sirtex and is now going
24 to do TheraSphere versus someone who has never done
25 any case of any kind and has just finished 3 cases of

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1 TheraSphere and is now going to do the fourth case on
2 your relative?

3 MEMBER LIETO: Yes.

4 MEMBER NAG: Which would you rather
5 prefer?

6 MEMBER LIETO: Yes because he's
7 experienced for the type of use he's going to be
8 doing, not the one he's not trained for.

9 MEMBER WILLIAMSON: Ralph, you're
10 consistent.

11 (Laughter.)

12 MEMBER NAG: And that's all that I'm
13 saying, that if you have done microspheres, that is
14 all that you need, not which kind of microsphere.

15 MEMBER WILLIAMSON: Yes.

16 MEMBER NAG: That was my point. You would
17 rather like someone who was experienced in microsphere
18 and is just changing the type of microsphere. I'm
19 taking your own question.

20 CHAIRMAN MALMUD: Thank you.

21 We have a comment from Debbie.

22 MEMBER GILLEY: I am enjoying this.

23 (Laughter.)

24 MEMBER GILLEY: First, I have two
25 questions. First is I believe this was a

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1 brachytherapy sealed source device registry part.
2 When did it move over to radiopharmaceutical therapy?

3 MEMBER LIETO: It's not.

4 MEMBER GILLEY: Okay. But you're now
5 looking at allowing nuclear medicine therapy
6 physicians to administer it because it's a Part 1000?

7 MEMBER NAG: In addition.

8 MEMBER GILLEY: In addition to the
9 brachytherapy. Okay.

10 The second thing is, could you please
11 define for me, what is supervision? Because I have
12 four different definitions of supervision in my
13 regulations. I have direct supervision. I have
14 remote supervision. I have supervision. And I have
15 general supervision. So which one of the supervision
16 is this? Because they all have very specific meanings
17 to them.

18 CHAIRMAN MALMUD: Does anyone wish to
19 address the answer to that question?

20 DR. HOWE: I will try, but I probably will
21 not be too successful.

22 (Laughter.)

23 DR. HOWE: In this particular case, we're
24 not talking about the supervision that you see in
25 35.27 because the supervision in 35.27, your

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1 authorized user doesn't have to be anywhere near the
2 department. We are talking about supervised work
3 experience.

4 And I think there is an understanding in
5 supervised work experience that the supervising person
6 is at least there to help supervise the work
7 experience. So the person getting the supervised work
8 experience has hands on. And there is someone there
9 guiding them.

10 MEMBER EGGLI: The answer to your question
11 is direct supervision.

12 MEMBER GILLEY: Well, if that is the
13 intent, then that needs to be specifically stated. If
14 not, the way it is written out, the supervision could
15 be removed. It doesn't have to physically be --

16 CHAIRMAN MALMUD: We have a member of the
17 public.

18 MR. WHITE: You raised an issue that
19 transcends this particular issue. And that is the
20 issue of supervision. I would just like to suggest
21 that as you consider this, you think about the CMS
22 definitions for supervision, widely accepted
23 throughout the federal government and also adopted
24 recently by ASTRO and the American College of
25 Radiology in these contexts.

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1 And that is a general supervision. The
2 supervisor is generally responsible for what is going
3 on, has taken the responsibility for training of the
4 individuals and delegating them tasks but need not be
5 physically present; direct supervision, in which the
6 individual exercises general supervision and is
7 physically present within the facility available for
8 consultation during the procedure, if necessary.

9 And the third is personal supervision.
10 And that is where the practitioner, the supervisor, is
11 physically present at the site of the procedure; that
12 is, in the room essentially at the bedside.

13 And, rather than reinvent categories of
14 supervision, you might consider those three levels,
15 which are, again, widely accepted in use in other
16 contexts and I think define the possible universe of
17 supervisory activities.

18 CHAIRMAN MALMUD: Thank you. Gerald
19 White.

20 Dr. Williamson?

21 MEMBER WILLIAMSON: Well, I think the word
22 "supervision," then, has a problem in this context
23 because the vendor's representative or the remote
24 authorized user from some other license has no
25 standing or authority in the institution to make

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1 medical decisions for that patient.

2 I mean, this is a patient of the physician
3 being trained. And that physician must be responsible
4 for the decision-making. So it is impossible to use
5 the word "supervision" in this context.

6 MEMBER WELSH: Can I make a comment there?

7 CHAIRMAN MALMUD: Yes, please, Dr. Welsh?

8 MEMBER WELSH: In most, in at least some,
9 of the supervision provided by vendors, the one who is
10 seeking authorized user status goes to an institution
11 where they might do three or four cases a day and so
12 will be getting direct supervision from an authorized
13 user at an institution where that person who is the
14 authorized user does have privileges at the hospital
15 answering that point.

16 MEMBER NAG: No. I am telling you he will
17 be an observer. He is not performing the procedure.
18 So he has not been supervised. You know, he is an
19 observer there. If you go to another institution,
20 that is the basin in that institution. So you are an
21 observer at that institution. That is not supervised.
22 You are not being supervised there. You are an
23 observer. You are learning.

24 Then when you do it in your institution
25 and you have someone else coming in, authorized user

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1 or vendor, then you are being supervised.

2 MEMBER WILLIAMSON: In some sense.

3 CHAIRMAN MALMUD: Dr. Thomadsen?

4 MEMBER THOMADSEN: What the supervising
5 external person is mostly doing is monitoring in this
6 case, rather than supervising, to throw an additional
7 possible word into the mix.

8 CHAIRMAN MALMUD: We do have a motion on
9 the table. And that is the motion which Dr. Nag had
10 made and was amended. Do you recall the motion?

11 MEMBER NAG: Yes.

12 (Laughter.)

13 CHAIRMAN MALMUD: Would you like to call
14 for a vote for the motion?

15 MEMBER NAG: Go ahead.

16 CHAIRMAN MALMUD: All right. Now, all of
17 those in favor of Dr. Nag's motion? Do you want to
18 repeat your motion briefly?

19 MEMBER NAG: The motion is that the
20 individual must have work experience, including at
21 least three cases of Yttrium-90 microspheres.

22 CHAIRMAN MALMUD: Deleting the words "for
23 each type of."

24 MEMBER NAG: Right.

25 CHAIRMAN MALMUD: And otherwise the

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1 statement is fine?

2 MEMBER NAG: Yes. And the second one I am
3 not even worried too much. "An authorized user is
4 someone who is experienced." I mean, the idea is it
5 has to be done in the presence of someone who is
6 experienced and knowledgeable.

7 MEMBER WILLIAMSON: I think that my
8 amendment was that for each type of medical device,
9 that the physician to become an authorized user
10 undergo the training program recommended by the
11 specific vendor.

12 MEMBER NAG: Right.

13 MEMBER EGGLI: Jeff, would you consider
14 amending that further to incorporate the language in
15 690?

16 MEMBER WILLIAMSON: Yes. So I would
17 recommend, yes, replacing this whole thing by the 690.

18 MEMBER NAG: The second paragraph with
19 language similar to 690.

20 MEMBER WILLIAMSON: Yes.

21 MEMBER NAG: Agree.

22 CHAIRMAN MALMUD: So the motion, then, is
23 to accept the first clip of the paragraph, omitting
24 the words "for each type" and then in the second
25 paragraph it being substituted with the existing

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1 language from 690?

2 MEMBER NAG: Yes.

3 CHAIRMAN MALMUD: All in favor?

4 (Whereupon, there was a show of hands.)

5 CHAIRMAN MALMUD: Opposed?

6 (Whereupon, there was a show of a hand.)

7 CHAIRMAN MALMUD: One opposed.

8 Abstention?

9 (Whereupon, there was a show of hands.)

10 CHAIRMAN MALMUD: Two abstentions, three
11 abstentions. How many? Four. Five. Five. Five are
12 for, three abstentions, and one opposition. Close
13 one.

14 CHAIRMAN MALMUD: Thank you for having
15 brought such a noncontroversial item before us.

16 MS. TULL: You haven't seen the next slide
17 yet.

18 (Laughter.)

19 MS. TULL: I'm not even going to put it up
20 there.

21 MS. WASTLER: Don't even put it up there
22 yet.

23 MS. TULL: Yes. Maybe we should go to
24 lunch.

25 MS. WASTLER: The question is, do we want

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1 to continue? It's noon. I know everyone is sitting
2 here probably getting hungry. Do we want to take this
3 opportunity for a breaks?

4 CHAIRMAN MALMUD: The Chair defers to the
5 wishes of the majority of the Committee. All of those
6 in favor of lunch immediately raise your hand.

7 (Whereupon, there was a show of hands.)

8 MEMBER NAG: Before that, the question is,
9 how are we going to make up the rest of the time?

10 MS. WASTLER: That's an issue we'll have
11 to discuss over lunch.

12 CHAIRMAN MALMUD: That is the second
13 question.

14 MEMBER LIETO: As soon as we finish this
15 issue. I would like to finish what Ashley has first.

16 CHAIRMAN MALMUD: No one was in favor of
17 lunch immediately.

18 MS. WASTLER: Okay. Go ahead, Ashley.

19 MS. TULL: All right. I will preface this
20 by saying --

21 MS. WASTLER: First take a deep breath.

22 MS. TULL: Yes. Everyone breathe.

23 MS. WASTLER: Take a deep breath. Okay.

24 MS. TULL: This presentation --

25 MS. WASTLER: This was prepared before

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1 yesterday's discussion.

2 MS. TULL: Yes. And --

3 MS. WASTLER: Okay.

4 MS. TULL: Be nice.

5 MS. WASTLER: Go for it.

6 MS. TULL: Attestation. This is
7 paralleling the current NRC regulations. That's why
8 we proposed this change. It was not recommended by
9 ACMUI at the April 2006 meeting. This is an NRC staff
10 change.

11 MS. WASTLER: Based on yesterday's
12 discussion, we understand exactly what the latest
13 position is.

14 MS. TULL: Yes. Is there a specific
15 recommendation to reword this based on yesterday's
16 discussion?

17 CHAIRMAN MALMUD: Who among the members of
18 the Committee would like the opportunity to reword
19 this?

20 MS. WASTLER: Again, this is draft
21 guidance. So while we might not be able to --

22 MEMBER EGGLI: I will take a shot at one
23 word.

24 MS. WASTLER: -- do much with regard to
25 how it has been written in 35, as it currently exists,

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1 this is guidance.

2 CHAIRMAN MALMUD: Dr. Eggli?

3 MS. WASTLER: So we have the opportunity
4 of possibly putting forth some of what you have
5 recommended yesterday, shall we say, as a trial
6 balloon? Because it does have to go through OGC.

7 CHAIRMAN MALMUD: Dr. Eggli?

8 MEMBER EGGLI: I would change one word.
9 In the third line up from the bottom, "competency," I
10 would change that word to experience and then say "An
11 individual must obtain written attestation signed by
12 a preceptor stating that the individual has
13 satisfactorily completed training and experience
14 requirements and has achieved a level of experience
15 sufficient to function independently as an authorized
16 user for the medical use of Y-90 microspheres." I
17 would change one word.

18 MEMBER WILLIAMSON: I would offer a
19 further amendment. Starting with the three dots, dot,
20 dot, dot, I would delete the remainder of the
21 paragraph.

22 MEMBER NAG: I was going to suggest the
23 same thing, "stating that the individual has
24 satisfactorily completed training and experience
25 requirements."

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1 MEMBER WILLIAMSON: Period, period,
2 period.

3 MEMBER EGGLI: I could go there.

4 MEMBER WILLIAMSON: Yes, period.

5 MEMBER NAG: "As an authorized user."

6 MEMBER WILLIAMSON: Period, yes.

7 MS. TULL: Ron?

8 CHAIRMAN MALMUD: Are you suggesting that
9 the sentence end at the word "requirements" or that
10 you leave out the "and has achieved a level of
11 competency"?

12 MEMBER EGGLI: Just the whole thing ends
13 at "requirements."

14 MEMBER NAG: Just say "completed the
15 training and experience requirements through function
16 as a authorized user."

17 MEMBER WILLIAMSON: I don't think that is
18 necessary. I think you can just end at the word
19 "requirements."

20 MEMBER NAG: Right. That's fine.

21 MEMBER WILLIAMSON: Okay. So the three of
22 us agree.

23 CHAIRMAN MALMUD: So the three of you are
24 making a motion that that be accepted with the word
25 "requirements" being the last word, followed by a

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1 period?

2 MEMBER WILLIAMSON: Yes.

3 CHAIRMAN MALMUD: That is your motion?

4 MEMBER WILLIAMSON: Yes.

5 MEMBER NAG: Yes.

6 CHAIRMAN MALMUD: Okay. Any further
7 discussion of that motion? Behind me, member of the
8 public?

9 MS. FAIROBENT: Lynne Fairobent, AAPM. I
10 think that before you delete what comes after the
11 ellipsis, you need to look at the written text to get
12 the full statement that precedes the ellipsis, which
13 is "training and experience described above." Without
14 the "described above" after "requirements," it could
15 be training and experience for anything.

16 MEMBER NAG: Right.

17 MS. TULL: I see what you're saying.

18 MS. FAIROBENT: Yes.

19 MS. WASTLER: So we would have to --

20 MS. TULL: It might have --

21 MS. WASTLER: So you would have to refer
22 to the training and experience as described.

23 MS. FAIROBENT: But as this motion, it
24 would not include "as above."

25 MS. WASTLER: Okay.

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1 CHAIRMAN MALMUD: You are correct.

2 MS. FAIROBENT: And then I have a
3 question. Is the "signed by a preceptor" given
4 yesterday's discussion going to be tabled depending on
5 what happens with that discussion?

6 CHAIRMAN MALMUD: We were going to go to
7 lunch, Lynne.

8 (Laughter.)

9 CHAIRMAN MALMUD: May we take this as a
10 two-step process? The first step -- oh, excuse me.
11 Dr. Schwarz?

12 MEMBER SCHWARZ: I have a question. In
13 terms of 690 uses, what exactly is required that the
14 authorized user obtain currently?

15 CHAIRMAN MALMUD: In terms of the 690
16 uses, what is required with the authorized user
17 obtained currently? And I will defer to Dr. Howe for
18 an answer to that question.

19 DR. HOWE: Okay. If you are already a 690
20 user, then you have to receive training in device
21 operation safety procedures, clinical use of the types
22 for which your authorization is sought. And it can be
23 obtained from any one of a number of ways.

24 But you also have to have obtained a
25 written attestation that the individual has

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1 satisfactorily completed the requirements in
2 paragraphs -- and that was paragraph C, so there is a
3 requirement for paragraph C of this section -- and has
4 achieved a level of competency sufficient to function
5 independently as an authorized user for each type of
6 therapeutic medical use for which the individual is
7 requesting authorized use or status.

8 And the written attestation must be signed
9 by a preceptor authorized user who meets the
10 requirements in 690 or equivalent agreement state and
11 is authorized for the type of use that you're applying
12 for. That's the current requirement.

13 CHAIRMAN MALMUD: Thank you for clarifying
14 that.

15 Dr. Williamson?

16 MEMBER WILLIAMSON: Well, I think then we
17 could amend the motion to basically delete the entire
18 paragraph since the individuals who have come forth as
19 authorized user candidates already have signed
20 attestations for either 35.300 uses or 35.400 uses,
21 which should suffice.

22 And if we're taking more the analogy that
23 we are treating this like adding another modality to
24 one of these broader armamentariums covered by 34.400,
25 then there shouldn't have to be a preceptor statement.

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1 There only needs to be on record, you know, if called
2 to defend it documentation that they have completed
3 the vendor-recommended training program.

4 CHAIRMAN MALMUD: Dr. Howe?

5 DR. HOWE: If I could make a quick
6 comment? If you want to use the model in 390, then
7 the model is that you have clinical experience and the
8 preceptor authorized user has to have clinical
9 experience in what you are applying for also.

10 So the modality would be this would be an
11 additional modality that you would need new
12 authorization for. And in 690, it would be the same
13 concept. This would be an additional modality that
14 you would need an additional preceptor attestation
15 for. So that is the current regulatory model that is
16 in existence.

17 CHAIRMAN MALMUD: Mr. Lieto?

18 MEMBER LIETO: I am going to make a
19 suggestion, which goes along, that would support the
20 travesty of the previous slide that replacing the word
21 "preceptor" with the supervising manufacturer's
22 representative. So basically the person that
23 supervises the training and experience attests that
24 they have satisfactorily completed.

25 It's not the preceptor. So it's not an

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1 authorized user but simply change the word "preceptor"
2 to something like the "training manufacturer's
3 training supervisor" or whatever term you want to use,
4 the person that's there supervising the training --

5 MEMBER WILLIAMSON: An individual
6 supervising the training in paragraph whatever. I
7 think that would solve it. Yes. So "Individuals must
8 also obtain written attestation signed by the
9 individual supervising the training in paragraph" X,
10 "stating that the individual has satisfactorily
11 completed the training and experience requirements,"
12 period. How is that?

13 CHAIRMAN MALMUD: You are using the word
14 "individual" twice and referring to two different
15 individuals. So you might want to use a synonym for
16 individual.

17 MEMBER WILLIAMSON: Okay.

18 CHAIRMAN MALMUD: Something to clarify.
19 Is that a motion, Dr. Williamson?

20 MEMBER WILLIAMSON: Yes.

21 CHAIRMAN MALMUD: Is there a second to Dr.
22 Williamson's motion? There's no second.

23 PARTICIPANT: There is a second.

24 MEMBER SCHWARZ: Dr. Malmud, Debbie just
25 made a comment.

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1 MEMBER GILLEY: Why don't you just put
2 that they have to complete a manufacturer-specific
3 training and provide documentation when completing the
4 manufacturer-specific training program? That says the
5 same thing, I think, with a lot fewer words and very
6 clearly.

7 MEMBER WILLIAMSON: We were trying to
8 comply with their regulatory model. That was why.
9 But if your OGC will let it by without having to have
10 reference to that model, hey, I would agree completely
11 with Ms. Gilley's proposal.

12 MS. TULL: The current guidance does read
13 "Authorized users must meet the training and
14 experience requirements of the specific vendor
15 training."

16 PARTICIPANT: Yes.

17 MS. TULL: If that is what you are asking
18 for, that is in there. In the second paragraph of the
19 guidance, it's the first sentence. That would be
20 covered.

21 MEMBER GILLEY: Then why would you need
22 this at all?

23 MEMBER WILLIAMSON: Yes. Then I would say
24 delete this paragraph if possible.

25 CHAIRMAN MALMUD: It is suggested that

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1 this is an unnecessary addition?

2 MS. WASTLER: What it doesn't convey I
3 think that Debbie Gilley was providing is written
4 documentation that the authorized user has completed
5 the training. That's the piece that is missing.

6 MS. TULL: We could make it say they must
7 meet and document --

8 MEMBER NAG: Then add that in that
9 previous paragraph, then, when you're talking about
10 manufacturer's training.

11 MR. THURSTON: Yes. Both manufacturers
12 currently provide such documentation that the new user
13 has indeed completed the training. However, we cannot
14 sign off on the competency of the individual, but we
15 do provide the other --

16 MS. WASTLER: I'm sorry. I didn't --

17 MR. THURSTON: The manufacturer can't
18 attest to the competency of the individual in this
19 therapy. We can provide documentation that they have
20 been through our training, our radiation safety
21 procedures, and have been duly monitored and
22 supervised by the appropriate representative. And we
23 do currently provide that for every site, both
24 manufacturers.

25 MS. WASTLER: Understood. Thank you.

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1 CHAIRMAN MALMUD: Therefore, what is the
2 motion currently on the table?

3 MEMBER WILLIAMSON: The motion is to
4 delete this paragraph and incorporate in the paragraph
5 described by Ashley "requiring completion of the
6 vendor training, that written documentation of same be
7 retained."

8 CHAIRMAN MALMUD: That is the motion?

9 MEMBER WILLIAMSON: Yes.

10 CHAIRMAN MALMUD: Is there a second to
11 that motion?

12 MEMBER NAG: Second.

13 CHAIRMAN MALMUD: Dr. Nag seconded it.
14 Any further discussion of that motion?

15 (No response.)

16 CHAIRMAN MALMUD: All in favor?

17 (Whereupon, there was a show of hands.)

18 CHAIRMAN MALMUD: Any opposed?

19 (No response.)

20 CHAIRMAN MALMUD: Any abstentions?

21 (No response.)

22 CHAIRMAN MALMUD: Unanimous.

23 MS. TULL: I am impressed.

24 (Laughter.)

25 MEMBER NAG: I have a motion that we break

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1 for lunch.

2 CHAIRMAN MALMUD: Dr. Nag has a motion
3 that we adjourn for lunch.

4 MS. TULL: We're getting to the end. That
5 was the worst part. That was the worst part.

6 MS. WASTLER: There are only three more.

7 CHAIRMAN MALMUD: Ashley's suggestion is
8 that we try and plow ahead.

9 MEMBER NAG: Okay.

10 CHAIRMAN MALMUD: Go ahead, Ashley.

11 MS. TULL: Okay. Team approach, again
12 taken from the April 2006 meeting, -- this came
13 directly from the transcript -- now reads "Microsphere
14 brachytherapy treatment is usually conducted using a
15 multidisciplinary team approach. The AU should
16 consult, as necessary, with individuals with
17 experience in oncology, catheter placement, radiation
18 dosimetry, and safe handling of unsealed byproduct
19 material." And we also added that one individual may
20 satisfy more than one of the listed areas of
21 expertise.

22 Any problems with that?

23 MEMBER NAG: No problem. That was the
24 same thing we had in our --

25 PARTICIPANT: We agree. We agree. Go.

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1 CHAIRMAN MALMUD: Comment?

2 PARTICIPANT: Call for the question.

3 MR. WHITE: Gerald White, AAPM. I'll just
4 call to your attention that the American College of
5 Radiology and ASTRO have described the process of care
6 for these procedures. It's very detailed, and it's
7 described most recently in the ACRS drug coding guide.

8 I would urge both the Committee and the
9 NRC to review the process of care for this procedure
10 because it's much more specific than what is described
11 in this slide.

12 I think it would be preferable if the NRC
13 did not reinvent the process of care that the medical
14 community has already agreed on. In particular, there
15 is no mention of medical physics in this list, but I
16 will refer you to the general descriptions in the
17 ASTRO process.

18 CHAIRMAN MALMUD: Dr. Nag?

19 MEMBER NAG: Yes. I mean, we went over
20 this with the Committee. And the reason why it was
21 worded this way is that in some centers the oncology
22 class may be provided by a medical oncologist, by a
23 radiation oncologist.

24 Catheter placement would be provided by
25 interventional radiologists or by other radiologists.

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1 The radiation dosimetry would be by a dosimetrist or
2 an AMP. And safe handling in many places is done by
3 a physicist or an RSO. That's why we have put it that
4 way.

5 CHAIRMAN MALMUD: Yes, Dr. Eggli?

6 MEMBER EGGLI: I think this description
7 covers the categories of expertise required without
8 specifically naming individual roles that are required
9 to satisfy. I prefer the more generic description.

10 CHAIRMAN MALMUD: Dr. Welsh?

11 MEMBER WELSH: My concern is with the term
12 "oncology." In this country, the reality is that
13 oncology is synonymous with medical oncology to 99
14 percent of medical practitioners. As written, it
15 could be misinterpreted to mean medical oncology when
16 I think we mean an individual with expertise in
17 oncologic management of cancer patients.

18 MEMBER NAG: No problem there, I mean,
19 excepting oncology you can take cancer treatment.

20 MEMBER WELSH: As written now, it would be
21 interpreted as medical oncology by 99 percent of
22 medical people.

23 MEMBER EGGLI: Could you put in
24 parentheses "medical and/or radiation" behind it?

25 MS. TULL: To answer your question, we did

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1 have that in there at one point. I did have
2 parentheses because that came out in the transcript.
3 And then through many, many, many revisions, we took
4 it off and just said "oncology" to keep it as broad as
5 possible.

6 If you guys want to bring it back to more
7 specifics, I don't think NRC staff is opposed to that.

8 CHAIRMAN MALMUD: Dr. Thomadsen?

9 MEMBER EGGLI: It's not broad as written.

10 MEMBER THOMADSEN: Well, sort of to that
11 point, I would have assumed that the oncology here
12 being basically a radiation oncology, is more to the
13 point, somebody who is well-versed in the biological
14 and medical effects of high doses of radiation in body
15 organs and systems, which a medical oncologist would
16 not -- leaving that open for a medical oncologist
17 would be a mistake in that case.

18 CHAIRMAN MALMUD: The motion was to
19 approve it as is. Is there an amendment to the motion
20 or should we --

21 MEMBER NAG: I would amend the word
22 "oncology" be replaced by "with expertise in" --

23 CHAIRMAN MALMUD: "Cancer treatment"?

24 MEMBER NAG: -- "cancer treatment."

25 CHAIRMAN MALMUD: Dr. Thomadsen?

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1 MEMBER THOMADSEN: That doesn't really
2 come to the issue because medical oncologists are
3 quite expert in cancer treatment. The point here is
4 high doses of radiation involved in --

5 MEMBER WILLIAMSON: We've got already an
6 AU who is either a 35.300 or a 35.400. That means the
7 person either has the broadest category of
8 radiopharmaceutical treatment, which generally is
9 radiation, often high doses, for oncologic management
10 or it's a radiation oncologist. So isn't it kind of
11 redundant to have the word "oncology" there? Why not
12 just strike it out?

13 MEMBER NAG: No because you need someone
14 who knows about cancer treatment for the overall
15 medical management of where the cancer is and so on.
16 I mean, if you want to put "cancer treatment" anyone
17 with experience in, well, radiation dosimetry there,
18 radiation dosimetry and radiation effects, you could
19 do that.

20 MEMBER WILLIAMSON: So you are not
21 satisfied that the AUs cover what is intended by
22 oncology? What is the problem?

23 MEMBER NAG: Oh, yes. Okay.

24 MEMBER WILLIAMSON: AUs are either 35.300
25 or 400 practitioners. So I am arguing that the

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1 reference to oncology, special reference to oncology
2 is unnecessary. So I think that if you just deleted
3 the word "oncology," it would be fine.

4 MEMBER NAG: No, no, it wouldn't. Delete
5 "oncology" but replace with "by someone with expertise
6 in cancer treatment." The reason for that is that AU
7 may not be a radiation oncologist. The AU may be a
8 nuclear medicine physician. So that would certify the
9 AU requirement.

10 MEMBER WILLIAMSON: I see.

11 MEMBER NAG: It can certify someone who
12 knows about radiation. But that person may not know
13 how to treat cancer. We want an expertise in cancer
14 in that.

15 So I think I agree with Jim Welsh that
16 oncology may be misinterpreted as medical oncology.
17 And, therefore, I would say "individual with expertise
18 in cancer treatment," "cancer management."

19 MEMBER WILLIAMSON: All right.

20 CHAIRMAN MALMUD: Dr. Suleiman?

21 MEMBER SULEIMAN: I would like to propose
22 we table this, have a chance to review the standards
23 of care that Gerry White was just talking about. I
24 get a sense that this may not finish in the next
25 minute or two. And I think it would be nice to find

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1 out what else exists. And we have tabled some other
2 things.

3 CHAIRMAN MALMUD: There is a motion to
4 table the discussion for the moment.

5 MS. TULL: This does conclude the major
6 changes.

7 MEMBER NAG: In that case, I mean --

8 MS. TULL: There are other changes, but
9 this is basically it.

10 MEMBER EGGLI: A motion from Mr. Lieto?

11 MEMBER NAG: I would like to make a motion
12 that we accept it as.

13 PARTICIPANT: A motion to table trumps all
14 other motions.

15 CHAIRMAN MALMUD: Mr. Lieto, are you
16 seconding the motion to table?

17 MEMBER LIETO: No, I'm not going to. No.

18 CHAIRMAN MALMUD: Okay.

19 MEMBER LIETO: Thank you.

20 CHAIRMAN MALMUD: There is a motion to
21 table. All in favor of the motion to table?

22 MEMBER EGGLI: It wasn't seconded.

23 CHAIRMAN MALMUD: Is there a second to the
24 motion to table?

25 (No response.)

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1 CHAIRMAN MALMUD: All right. There is no
2 second to it. Okay. We move ahead with the motion on
3 the table.

4 MEMBER NAG: I would like to make the
5 motion that we accept it as is, replacing the word
6 "oncology" with "expertise in cancer management."

7 CHAIRMAN MALMUD: So "oncology" should be
8 replaced with "cancer management." That would include
9 medical, surgical, and radiation oncologists.

10 MEMBER WILLIAMSON: I second.

11 CHAIRMAN MALMUD: It has been seconded by
12 Dr. Williamson. All in favor of this change?

13 MEMBER NAG: Or any discussion?

14 CHAIRMAN MALMUD: Is there any discussion?
15 Mr. Lieto? Okay.

16 (Laughter.)

17 CHAIRMAN MALMUD: All in favor?

18 (Whereupon, there was a show of hands.)

19 CHAIRMAN MALMUD: Any opposed?

20 (No response.)

21 CHAIRMAN MALMUD: No opposition. Is there
22 an abstention?

23 (Whereupon, there was a show of a hand.)

24 CHAIRMAN MALMUD: One abstention. Okay.

25 Does that conclude it?

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1 MS. TULL: No.

2 CHAIRMAN MALMUD: No. One more item.

3 MS. WASTLER: These are very quick.

4 MS. TULL: Yes. These are minor changes.

5 If you guys don't even want to go over them, I mean,

6 it's in there.

7 CHAIRMAN MALMUD: I think that --

8 MS. TULL: We added a paragraph for limited
9 specific medical use licensees to state basically that
10 notification does not apply. You've got to come in
11 with a license amendment.

12 CHAIRMAN MALMUD: I didn't understand what
13 you said.

14 MS. TULL: Okay. We added a paragraph to
15 read, "An individual's qualifications to be an AU for
16 Yttrium-90 microspheres at a limited specific medical
17 use licensee site must be reviewed and approved by the
18 appropriate regulatory authority." So this means you
19 can't come in under notification according to 35.14.
20 35.14 would not apply.

21 MEMBER EGGLI: Only broad scopes can use
22 notification.

23 MS. TULL: Yes.

24 MEMBER EGGLI: Okay.

25 MS. TULL: Donna-Beth?

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1 DR. HOWE: Just a quick clarification.
2 The broad scopes don't have to notify NRC because
3 their radiation safety committee is the group that
4 approves.

5 MEMBER EGGLI: Move acceptance.

6 MS. TULL: Say it again.

7 MEMBER EGGLI: Move acceptance of that
8 provision.

9 MS. TULL: Okay.

10 CHAIRMAN MALMUD: Second? Any discussion?

11 (No response.)

12 CHAIRMAN MALMUD: All in favor?

13 (Whereupon, there was a show of hands.)

14 MS. TULL: Next point on this slide is
15 just waste disposal. There was an information notice,
16 which I believe I sent to the entire Committee. It
17 was talking about contaminants in the microspheres
18 that cause problems with waste disposal issues.

19 So you either have to keep it for longer
20 in decay and storage, send it back to the manufacturer
21 if they'll take it back, or send it to a waste
22 disposal facility.

23 There was an IN on that. We added a
24 paragraph saying we issued an IN on this, that change,
25 clarification, grammar, formatting, lots of that.

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1 We have two discussion topics that we were
2 going to ask for input from ACMUI. The first one is
3 what Dr. Suleiman brought up earlier as far as dose
4 versus activity. NRC's current guidance is written
5 with dose to mean dose, absorbed dose, not activity,
6 dose in gray.

7 Manufacturers currently use millicuries or
8 gigabecquerels in their inserts.

9 MEMBER NAG: I would like to table what is
10 going to be a long discussion. And we can't do it
11 now.

12 PARTICIPANT: I agree.

13 CHAIRMAN MALMUD: It has been moved and
14 seconded to table it. And I would suggest that we
15 adjourn for lunch.

16 Now I have been informed that our next two
17 speakers, Drs. Katz and Ansari, have already been
18 placed in a position where they have to change their
19 flights out because they flew in expecting to speak
20 this morning. So we will resume. And then they will
21 be, obviously, the next two items on the agenda. And
22 I apologize to them for the need to reschedule.

23 Be back here at 1:00 o'clock. Thank you.

24 (Whereupon, a luncheon recess was taken
25 at 12:18 p.m.)

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1 DR. MALMUD: We have with us today Drs.
2 Armin Ansari and Luba Katz from Atlanta, and Boston,
3 respectively, who will make the next presentation on
4 the release of individuals containing byproduct
5 material in the context of radiation monitoring at
6 security checkpoints. And you're on.

7 DR. ANSARI: Thank you. Thank you very
8 much. Just a little more introduction. I'm a health
9 physicist with the Centers For Disease Control and
10 Prevention in Atlanta, and Dr. Katz is a scientist
11 with Abt Associates, who had the contract through
12 Agency For Health Care Research and Quality, to do the
13 survey that you will hear about today, and she
14 analyzed all the data for us.

15 I'd also like to thank the NRC, and
16 specifically Ms. Flannery, for the support that they
17 provided for the project that you will hear about, and
18 thank this committee for having us here to share our
19 data with you.

20 I know Ms. Flannery, in the last meeting
21 of this committee, briefly introduced the project, and
22 I'll just take a brief moment to tell you why the
23 interest in this topic and how we did the summary and
24 the way we did it, and might also explain why the long
25 title that we have for the presentation.

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1 We have all heard about the patients
2 having issues at security checkpoints. They are all
3 anecdotal accounts, some news clippings here. We know
4 how serious that problem is, how much of a nuisance it
5 is, how frequent it is, and we also observed that
6 there's a varying degree of being informed on the part
7 of the patients. This is all again anecdotal, from
8 what we heard, and some of our colleagues, friends,
9 and family members.

10 So we knew about the issues about maybe
11 unnecessarily alarming patients. We knew about the
12 issues of providing documentation to patients as they
13 travel. We knew about the NRC information notice of
14 2003, which we'll describe here. It was out there,
15 and, you know, within that background, we thought it
16 might be a good idea, since there was no other
17 information out there, to go ahead and survey a number
18 of health care providers and see what the actual
19 practice is, how they actually handled this situation,
20 get a range of practices and communicate that
21 information, provide that information, perhaps a best
22 practice can be identified and communicated.

23 So that was the intention of the project.
24 Originally, there was some misunderstanding about what
25 the project was about. Some folks thought that this

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1 was looking at compliance issues of existing
2 regulations, something that clearly is in the domain
3 of the NRC and state regulatory agencies, but this was
4 not at all the intention of the survey.

5 So that's part of the long title, in the
6 context of radiation monitoring at security
7 checkpoints. That's what the driver was.

8 So this is just to say that anything
9 unintelligent you hear from me is not--you don't hold
10 our employers responsible.

11 Just a few news clippings, just to show
12 you the flavor of what's out there. This is last
13 month, May of 2007, in the Seattle Times. "Bomb on
14 board the ferry." This is a story about how Charlie
15 was mistaken for a nuclear weapon and it begins during
16 a trip to the cardiologist.

17 So sensationalized reporting. Another
18 example from March, radiation data. This was in
19 Connecticut. A lady was driving in a car and
20 Connecticut law enforcement was passing her and they
21 happened to notice the, it tripped the sensor, so they
22 stopped her. This is a quote. She said nobody at my
23 doctor's office warned me this would happen.

24 This was also in January, right before the
25 Super Bowl, and what was interesting in this story, it

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1 was warning fans going to the stadium to be prepared
2 in case there's--well, they also mentioned an incident
3 during a Christmas tree lighting ceremony in
4 Rockefeller enter early in November, when the New York
5 police had pulled six people and questioned them.

6 And what was interesting is two quotes in
7 there of two people that they talked. One of them
8 said it happens all the time. The other one says it
9 had been infrequent. Different perspectives.

10 This one also was a Canadian gentleman,
11 radioactive prostate, sets off airport alert, and what
12 was interesting about here is iodine seeds in
13 prostate, the patient stopped, and the patient knew
14 very well why he set off the alarm and tried to
15 explain it to the agent who stopped him. But the
16 agent had not heard of such a procedure.

17 But fortunately for the patient, the
18 agent's supervisor's brother-in-law had a similar
19 procedure, so they let him go, indicating that there's
20 also issues with people that are actually doing the
21 screening, not perhaps being as knowledgeable as they
22 should be.

23 This account was published by the
24 patient's doctors in the Canadian Medical Association
25 Journal, and they said in that article, the day after,

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1 the state decided to actually go ahead and provide
2 documentation to all of their patients from the on.

3 When we look at the literature, the
4 earliest that we can find is something that was in a
5 letter to the editor of New England Journal of
6 Medicine 20 years ago, problems on Pennsylvania
7 Avenue. Very interestingly, two of the patients from
8 the University of Cincinnati Medical Center, a few
9 months apart, thallium patients, they had gone to take
10 the White House tour and were stopped by Secret
11 Service.

12 And what was interesting about this
13 recommendation is that the doctors thought, perhaps
14 rightly so, that this was a very isolated--you know,
15 only happens if you take the White House tour.

16 And because these radiation screenings
17 were not as extensive as they are today. So they
18 said, you know, issue one if they plan to go to the
19 White House.

20 Two years later, a similar letter to the
21 New England Journal of Medicine from Washington
22 University School of Medicine. This was a patient who
23 had actually gone to check his safety deposit box in
24 a bank, and that tripped the alarm. Interestingly,
25 the bank had installed this because they were

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1 concerned about clients leaving radioactive materials
2 in a safety deposit box.

3 So they also said it behooves all
4 physicians ordering, or administering a thallium test,
5 to warn their patients they may be radioactive. Of
6 course we know that now they can even remain that way
7 for longer than seven to ten days because the sensors
8 are much more sensitive.

9 Then I didn't find anything in the '90s.
10 What's in the literature now is actually post 9/11,
11 and this is a sampling. Interestingly, these are in
12 British journals mostly, Lancet and British medical
13 journal. The Lancet article is about a commercial
14 pilot who gets stopped, and the third item there is a
15 gentleman with the seeds, the prostate.

16 The article in Nuclear Medicine
17 Communications is this one, right here. One of the
18 authors is actually a member of the Institute for
19 Nuclear Medicine in Vienna, the Austrian agency, and
20 what they provided in their report, which I've copied
21 here, is actually a form, because after this happened
22 to one of the patients, they decided to have this form
23 and it actually has a lot of the information that we
24 now see in some of the documentation for providers
25 that provide them here. Even some of the language,

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1 similar to the NRC information notice. I'm sorry you
2 can't read this but it does say that dismissal of the
3 patient is in agreement with Austrian radiation
4 protection rules and regulations, similar to the NRC
5 suggested language in their information notice.

6 And they also here say that if it trips
7 the alarm, that this is not associated with any
8 radiation hazard to others. So that's the example
9 they provide.

10 Now this was another international who, at
11 Orlando, was interrogated. The fact that he was
12 strip-searched, dogs were brought in, kind of a, not
13 a very pleasant experience, and so they also
14 recommended that patients be warned about this, and
15 they said that doctors show a worrying lack of
16 awareness of such problems.

17 This is the NRC information notice I was
18 talking about, came out in December of 2003, and what-
19 -I'm not sure if that's the incident that triggered it
20 but the one incident that was mentioned in the
21 information notice was the gentleman who had iodine-
22 131, merely failed to follow the directions that was
23 given to him.

24 The day after his treatment, he's going
25 through Lincoln Tunnel on the way to Atlantic City.

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1 So it prompted--I don't know if this was what prompted
2 the information notice but the example that was given
3 there.

4 And in that information notice, the
5 doctors advise licensees to inform the patients about
6 the importance of following the instructions they're
7 given as they're released.

8 And two reasons were given for that. One
9 is to maintain doses as low as reasonably achievable
10 and the second is to reduce the probability of
11 something like that, which would inconvenience not
12 only the passenger but other people, and also law
13 enforcement.

14 Some of the language in the information
15 notice, if you look at the second bullet, it talks
16 about authorized users are expected to evaluate the
17 patient's capability to follow instructions before
18 release, and stress the importance of them following
19 the written instructions.

20 Even though the sentence starts with "when
21 required to provide written direction," NRC
22 acknowledges that even at levels below that, when
23 written instructions are not required, they still have
24 detectable radiation that would trip the alarms.

25 So then regarding all patients that have

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1 detectible amounts of activity that could trigger
2 alarms, they offer two voluntary actions. One of them
3 is to provide all patients with an appropriate
4 explanation on the potential for alarming radiation
5 monitoring equipment and second is that to consider
6 providing them with some kind of documentation and
7 information for law enforcement they can contact and
8 verify.

9 Later that December, American College of
10 Nuclear Physicians had this press release, essentially
11 saying what, the NRC information, and suggesting that
12 documentation that is provided to the patients include
13 that information.

14 This effort I believe was coordinated with
15 the Society For Nuclear Medicine, because later on,
16 they I believe asked the physicians to, if you
17 encounter any--if you hear anything from your
18 patients, please communicate that to us and let us
19 know, and that e-mail was an SNM.org e-mail. So one
20 thing is I'm going to follow up, actually, with Mike
21 Peters, if he's here, with Society of Nuclear
22 Medicine. We're going to move, follow up, and see if
23 any information was provided--we kind of doubt it but
24 we will see.

25 Speaking of Society For Nuclear Medicine

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1 they most recently had a press release in November of
2 last year, right before the holidays, asking the
3 medical community to make patients aware of the
4 security problems. Patients and health care providers
5 should discuss. And then they also said patients
6 should obtain a letter from their doctors that
7 contains the following information.

8 And it stressed the after-hours
9 availability of information, someone who has access to
10 appropriate information if they are contacted for a
11 verification.

12 So if all of that is not enough, I've got
13 a sound clip, just two minutes long, maybe this will
14 play, just as a last-minute thing. See if it plays.
15 It was a Paul Harvey piece right before the Super
16 Bowl, and was kind of just telling them that, people
17 that, you know, don't be surprised, if you're going to
18 the Super Bowl, get a note from your doctor. That
19 type of thing.

20 Now with this, we wanted to see what, as
21 I said, what kind of practices are out there. And
22 this is our methodology of what we follow. NRC, you
23 know, as I said earlier, was a tremendous help to get
24 this project done, developed a temporary instruction
25 for NRC inspectors, for the questionnaire Dr. Katz and

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1 I assisted Cindy to come up with a draft of the
2 questionnaire. Ms. Flannery sent that to NRC regions
3 for comment. We got their input and we had many good
4 comments from them.

5 And then this went into effect, temporary
6 instruction went into effect in October of 2006 for
7 three months.

8 Initially, we were hoping to---this was a
9 small project--we were hoping for thirty, I think--
10 well, we were--thirty minimum, and we were hoping for
11 sixty and we got 66 facilities serving, and then NRC
12 regional inspectors would send the data to
13 headquarters and Ms. Flannery would then share the
14 data with us, and Luba analyzed them for us.

15 Some limitations and advantages of this
16 approach. Of course this was limited to nonagreement
17 states, the way it was done. We also sort of, we had
18 to be careful about recognizing the responder's
19 candor. Has he been interviewed by NRC inspectors?
20 Might be an issue. This was done not as part of the
21 regular compliance type of inspection. It was done
22 outside of that.

23 But, you know, you're talking to an NRC
24 inspector, you want to put the, you know, present the
25 best light. So we were aware of that and this was

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1 certainly a limitation. And the third one, which is
2 last but not least, was that the--we not being able to
3 ask follow-up questions, because no matter how
4 carefully we devised the questionnaire, there were
5 some points, as we were reading them, that, I wish
6 we'd asked that for clarification or I wish we'd asked
7 that follow-up question.

8 So this was not possible to do. So these
9 were limitations. The advantages was actually very
10 valuable input that we got from NRC to draft the
11 questions, we got very good input from them, and the
12 kind of access that provided was very valuable.

13 In fact in several facilities, there was
14 more than one person and NRC inspectors, who had
15 access to those people to interview them, and the
16 other was a 100 percent response rate. If we were
17 doing it the original way, I know we were going to
18 have issues with those facilities that would not
19 participate, and therefore nonparticipating facilities
20 would introduce some kind of bias.

21 And we didn't have that here. So we had
22 a 100 percent response and that was an advantage.

23 The questionnaire had information about
24 general facility information, about the individual
25 being interviewed, and they were asked if they were

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1 familiar with the NRC information notice, and we asked
2 questions about how they do the informed consent, what
3 kind of information they provide to the patient and
4 who does provide the information.

5 We also asked them for copies, if they had
6 documentation they give to patients, to give copies
7 that we can see.

8 I think to go through these quickly, this
9 will be in the report that we will make available, and
10 so--but these slides are here just to show that even
11 though our sample size was sixty facilities and 89
12 people, it did cover a wide range, communicative
13 hospitals, number of beds, and also number of
14 procedures that were done annually.

15 We did have a range. These are the type
16 of procedures they do. This one just showing the
17 experience of the people who were interviewed, also
18 covered the range, people with 36 to 40 years of
19 experience, or less than one year, either in facility
20 or total experience. And also these are the people we
21 talked to, nuclear medicine and medical physicists and
22 RSOs and physicians.

23 A question with their familiarity with NRC
24 information notice. 85 percent said yes, they were
25 familiar with the information notice. This one, we do

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1 wonder a little bit, if this might be an exaggerated
2 number. Maybe we could have done the question a
3 little differently or something maybe to minimize that
4 but this was the answer we got. 85 percent said yes,
5 they are aware.

6 Of the remaining that were not, ten of
7 twelve were from outpatient diagnostic facilities. So
8 this is something that, in fact, one of our
9 observations at the end we talked about, this is a
10 target audience that maybe we need a little bit more
11 outreach with respect to this issue.

12 We asked them do you inform patients that
13 may activate radiation detectors. The radiotherapy
14 had therapeutic--we had these two sections, people who
15 do only therapeutic and radiotherapy and
16 radiopharmaceuticals. We separated those two. For
17 the therapeutics and radiotherapy patients, the
18 majority said yes, and the few that said no, one of
19 the reasons, well, it unduly alarms patients. Four,
20 diagnostics. It was sort of more said yes than no,
21 and 15 percent of respondents recalled actually being
22 contacted about a patient who was stopped, and some of
23 the examples they gave was at the U.S.-Canadian
24 border, two were nuclear power plants, and a landfill
25 truck driver at an unspecified location.

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1 And three of these, three of the
2 facilities that were contacted about actual patients,
3 still don't provide documentation.

4 The question, Do you provide
5 documentation? 65 percent actually said yes, they do
6 provide some sort of documentation, and pretty much
7 the rest of them, they provided, on request.

8 What formal documentation? Of the 43
9 facilities, 35 shared their documents with us, and I
10 will show you some examples of that. A few of them
11 were handwritten notes on prescription pads or blanks
12 pieces of paper, and this was generated during the
13 interview, and--

14 DR. KATZ: It did not look very
15 convincing.

16 DR. ANSARI: Whether to the law
17 enforcement, or when we even questioned, they would--
18 they did that for the inspector, we didn't know they
19 would do that for the patient. So usually the
20 information that's included is the radionuclide,
21 amount of activity, half-life, and twelve of the 35
22 documents we got actually, verbatim, repeat what was
23 in the NRC information notice, the suggested language,
24 that this radiation poses no danger to the public and
25 is allowed by the medical use regulations.

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1 But in a couple of cases, we saw some text
2 that really didn't, wasn't helpful to people who would
3 be looking at it, and you can see the example down
4 there. It was too technical. Most people looking at
5 it, either the patient himself or the law enforcement,
6 wouldn't know what that is.

7 Of the 27 respondents in a--this is for
8 the facilities that do not provide documentation, two-
9 thirds of them thought that what, the procedures they
10 had was adequate, so they were not impressed. They
11 didn't change anything.

12 And four of the individuals who do provide
13 the documentation, there were some suggestions, when
14 we asked could their procedure be improved, one of
15 them said yes, the access to patient information
16 during off-hours could be improved. We know that is
17 a problem with most of the facilities. Offering
18 documentation to all patients, other than just those
19 who are planning to travel. This was actually
20 something that was suggested in the NRC information
21 notice.

22 And one individual said that this should
23 be discussed at the regulatory level, which I know
24 most of the people did not agree with that.

25 And then last was one they should, the

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1 Government should install better equipment so they
2 don't harass patients, and I think that view was
3 shared by a lot of people too.

4 This is an example of one. Luba covered
5 the part about the facility name, but that was also
6 handwritten. The facility name was handwritten, and
7 this of course I don't think will offer any value.

8 This is a much better example,
9 CardinalHealth, but I want to pause on the last one,
10 which is, we thought was the best example of the
11 documentation we had. This is from the Barnes Jewish
12 Hospital, Washington University in St. Louis, and Dr.
13 Henry Royal provided this to us.

14 MEMBER SCHWARZ: Sally Schwarz.

15 [Laughter]

16 DR. ANSARI: Oh, okay.

17 MEMBER SCHWARZ: I am very definitely
18 aware of. Yes.

19 DR. ANSARI: But we did get permission
20 from Dr. Royal to publish this when we communicated
21 this information, as a really good example. In fact
22 I brought--David, you have three kinds. The one shown
23 here is generic. Is there just wallet-size cards?
24 Really convenient. One of them specifically for
25 iodine. The other one was technetium and thallium.

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1 But this one here is a generic one. It has everything
2 you want in the card, just put it in your wallet, and
3 the language and the instruction for patients is very
4 well-written, and also to the security people.

5 It even says to the security, that you may
6 be asked to let the patient confirm that the patient
7 has given you permission to release this information.
8 So it basically has everything in there, and when we
9 write this up for publication so everyone can see, we
10 plan to actually include this example.

11 We also asked some questions about how the
12 patient is informed, who talks to the patient, and it
13 really varied, about who gives this information to the
14 patient and then they do it, administration, before
15 the procedure.

16 One comment we included here was from an
17 inspector and it says in his view very little
18 information is provided regarding the nature of the
19 injected diagnostic agent. Some patients were told it
20 was radioactive or radiation, some were told it was
21 medication.

22 We asked--really, not "we." The
23 questionnaire included a question: How often do
24 patients express concerns or ask for additional
25 information? And this was a really broad range.

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1 There are eight facilities, that patients apparently
2 never ask questions, and in four facilities most
3 patients do ask questions.

4 And Luba really worked this data to see--
5 she can identify what is the reason. This was not due
6 to the staff years of experience. That didn't explain
7 it. The type of facility didn't explain it, and
8 whether or not the facility provides educational
9 material couldn't explain it.

10 There was some data that weakly suggested
11 that the training, communication training that the
12 staff had may explain this. But it was hard to do
13 this, statistically, with the numbers that we had. We
14 couldn't show it was the same, but it was suggested
15 that organizations that the staff had training in
16 patient communication, they're more likely to get
17 questions from the patient.

18 Now that would make sense, because when we
19 read the literature, I mean informed consent actually
20 says that personality and communication style of
21 individuals makes a big difference. If patient
22 regards the provider as approachable, they're more
23 likely to ask questions. So that would be consistent
24 with that.

25 Before we started doing this formal

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1 questionnaire with help of the NRC, we did sort of a
2 pilot thing, and this was Luba's introduction to
3 health physics and community, and medical physics
4 community, which was interesting. She will share that
5 with you privately, later.

6 But one of the things, one of the
7 interviews was actually really telling, and I don't
8 want to repeat verbatim of what was said during the
9 interview, it was a phone interview, but it was a
10 children's hospital and the kind of comments that were
11 made about patients asking questions about children
12 was kind of a--represented a cultural issue, of how
13 some people regard this issue, and I think it
14 highlights some of the training that needs to be done,
15 I think within this area. And this is the type of
16 answers that we probably would have gotten more, if
17 the survey was not done by NRC inspectors.

18 We were asked when the patients do express
19 concern about following instructions, what is their
20 number one concern. The number one concern seems to
21 be minimizing time with children and pregnant women,
22 maintaining distance.

23 Minimizing time in public was the least--
24 only one facility mentioned that as a concern, and I
25 think this also represents that, not that the patients

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1 don't think they can follow it, it's just that
2 patients are not concerned with that. They're more
3 concerned with minimizing time with their children.
4 They're not as concerned about being in public, so
5 they're less likely to follow that piece of the
6 instruction than the other.

7 We asked this question: Is it possible for
8 a patient to leave your facility without the knowledge
9 that they emit radiation?

10 The therapy, for the therapy in
11 radiotherapy patients, the answer was absolutely no,
12 it's not possible, and for diagnostic patients, 20
13 percent, 11 out of 54 who answered said yeah, it is
14 possible for them to leave the facility without
15 knowing. But the fault there is with the patient.
16 Some of them said patients may not understand what
17 we're telling them, they fail to understand
18 instructions, and not all patients have the same
19 knowledge, and not all of them retain information.

20 Specifically people with English as second
21 language, or elderly patients were specifically
22 mentioned there. But it was interesting that when
23 they gave the possibility that they may leave without
24 knowing, the fault was with the patient.

25 And this was also interesting. That 95

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1 percent of the respondents considered the procedures
2 adequate. And I think this might be also a side
3 effect of being interviewed by a NRC inspector,
4 because they're concerned, if we say it's not
5 adequate, what's going to come down the pike. More,
6 you know, more procedures, more regulations.

7 So this was understandable, that they
8 would kind a say that yes, you know, things are fine
9 and adequate.

10 We asked them, Do you have training in
11 patient education? It was sort of half and half.
12 Half of them said yes. This is self-proclaimed
13 training in patient education. Half said yes and half
14 said no. Then people who said no, we asked them, Do
15 you think that training would be beneficial?

16 And the majority thought that it would be
17 beneficial, but interestingly, a fraction of them, 28
18 percent, didn't think that it would be beneficial to
19 receive the training.

20 Of the ones who did say they received the
21 training, it was actually either by an RSO or
22 authorized user, during in-service, or residency, or
23 in a meeting. This was not very solid, even when they
24 did claim training. So this I think presented maybe
25 a need in that area.

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1 So these are the observations and
2 recommendations that we have looking at this data, is
3 that first, even though our sample size was not very
4 large, we think we captured the range of facilities
5 and practices. Diagnostic patients are less informed
6 than therapy patients.

7 And so in those facilities, the outpatient
8 diagnostic things could benefit from an improved
9 outreach. Staff may benefit from training in patient
10 education and communication. Most standardized
11 uniform documentation could be helpful, so we don't
12 get the handwritten stuff, and providing documentation
13 to all nuclear medicine recipients with potential to
14 set off alarms, could be helpful.

15 I'd like to acknowledge again Cindy
16 Flannery for her assistance and support, and all the
17 NRC inspectors, seventeen of them who collected this
18 data, and Ms. Palmer at AHRQ. And that's where we
19 are, and Luba is still working the data, and there are
20 some aspects of it that is in her report that's
21 preparing, but this is the nuclear presentation.

22 CHAIRMAN MALMUD: Thank you. Are there
23 questions? Comments?

24 MEMBER LIETO: So there's 78 total
25 responses, is that--

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1 DR. KATZ: Sixty-six facilities but each,
2 some facilities had more than one person that
3 inspectors spoke with, so it's 78 people.

4 MEMBER LIETO: Okay. Are you still
5 gathering data at the regional level, or that's cut
6 off? When was it cut off, date approximate?

7 DR. KATZ: It was between October and
8 November and December, three months, starting in
9 October.

10 DR. ANSARI: January. It was mid January,
11 was the cutoff date. We were shooting for sixty and
12 the temporary instructions had a provision for
13 extending it three more months.

14 MEMBER LIETO: I was going to say, they're
15 still handing that survey out.

16 DR. KATZ: They're still doing it?

17 MEMBER LIETO: They've been handing out
18 during the first quarter of this year, cause I had a
19 visit and I got one.

20 DR. KATZ: Okay. Well, that's good to
21 know because we did terminate the temporary
22 instructions. So obviously, someone didn't get the
23 termination--

24 [Simultaneous conversation]

25 MEMBER LIETO: Are just trying to gather

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1 information on certain--

2 DR. KATZ: Okay.

3 MEMBER LIETO: The inspector hands it
4 right to you.

5 DR. KATZ: Yeah.

6 CHAIRMAN MALMUD: Any questions of us?

7 DR. ANSARI: Well, I think this was what
8 we were thinking of doing with--and Mike, feel free to
9 please speak up--as a next step for us was to maybe
10 work with the Society For Nuclear Medicine, to see if
11 we can give this issue a little bit more exposure. I
12 think from our perspective, I think if recommendation
13 came, perhaps even with a form--like the Austrians
14 did--that was just a form. If a standard form was
15 provided by the NRC, something on the model of what
16 Washington University in St. Louis did, as an example,
17 then it kind of--that would be very helpful because
18 law enforcement are used to seeing and would be used
19 to seeing that form. The same-looking form for
20 everybody. And that would be really helpful.

21 The other thing that was helpful about
22 that form is it had two phone numbers. One was off-
23 hours, specifically. That would get them thinking,
24 look, if we provide a phone number here, somebody on
25 the other end, when they answer that phone, they're

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1 going to have access to that information.

2 I think that would probably be something,
3 if it came from a more authoritative source, providing
4 that example, it would be very helpful.

5 DR. KATZ: So I guess another comment that
6 we have is that we think the information which is,
7 that was put out, misled people, because the specific
8 example that was given was for iodine-131. So people
9 who do not administer this type of isotope thought,
10 oh, this has nothing to do with me, this is not my
11 isotope. There were several studies published when
12 people actually calculated for the modern detection
13 equipment, how long thallium and other, you know, very
14 prominently used isotopes, how long they are active in
15 setting off this alarm. So it's quite a long time.

16 But I think the community sort of is not
17 aware that this is the case, and that's why we notice
18 the diagnostic facilities are less concerned than
19 therapeutic facilities.

20 CHAIRMAN MALMUD: Dr. Williamson.

21 MEMBER WILLIAMSON: So what are the
22 threshold ambient exposure levels that tend to set off
23 these devices?

24 DR. KATZ: There is a paper by Zucker,
25 and, for example, a standard stress test, I think is

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1 something like 30 days within a room.

2 MEMBER WILLIAMSON: No, I asked what is
3 the exposure--

4 DR. KATZ: I don't remember the numbers.

5 DR. ANSARI: I think it sort of varies
6 like the, because of how some of these folks are
7 wearing it on their belt, and they are not as
8 sensitive as the portal type stuff, but I think twice
9 background is--

10 MEMBER WILLIAMSON: Yes. I think the
11 detection sensitivities are getting better and better,
12 so it's--I know 2mR per hour was the limit for one of
13 the detectors out there, but they designed detectors
14 to see almost anything.

15 MEMBER GILLEY: Twice background.

16 MEMBER WILLIAMSON: Yes.

17 MEMBER WILLIAMSON: But what was the most
18 frequently-observed nuclide? Do you know, or--

19 DR. ANSARI: The unfortunate thing is
20 about--and we tried to get data, nobody keeps that
21 data, to our knowledge. We've tried to actually--and
22 what we hear is anecdotal. Last week, I was at the
23 Georgia Emergency Management Conference, talking to a
24 gentleman who is familiar with Customs and Border
25 Protection, telling me about lots and lots of thallium

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1 hits. And I say, well, do they keep their data? Can
2 I get the data? And he said no, they don't.

3 CHAIRMAN MALMUD: Yes. Dr. Fisher?

4 MEMBER FISHER: I recently served three
5 years as science advisor at U.S. Customs and Border
6 Protection, with a responsibility in this area. The
7 sensitivity of the detectors is classified, of course,
8 and can't be stated in public, for obvious reasons.
9 The U.S. Customs and Border Protection has collected
10 a lot of data on the radionuclides detected at U.S.
11 border crossings, in terms of, you know, what's
12 causing the alarms. A large body of data on the
13 medical isotopes detected.

14 The agents are well-trained to recognize
15 medical isotopes and distinguish those from nonmedical
16 isotopes that might cause the alarms, and Customs also
17 has extensive 24-hour reach-back through their
18 Laboratories and Scientific Services Division, for
19 transmitting spectra of radioisotope detection, using
20 sodium iodide spectrometers.

21 And so that there's a 24-hour service,
22 where a scientist is on duty, can interpret a
23 spectrum, and quickly report back to the field if
24 there are any questions, and this service actually
25 works pretty well. At first glance, you might think

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1 it doesn't work but there's an extensive reach-back to
2 the field, and so we've seen a lot of examples where
3 at least the well-trained CBP agents really know what
4 they're dealing with when it comes to medical
5 isotopes.

6 CHAIRMAN MALMUD: Dr. Welsh.

7 MEMBER WELSH: I'd just like to say that
8 this is an excellent study and important information
9 If you are going to share this data with the Society
10 of Nuclear Medicine, I might recommend that you also
11 share it with the radiation oncology societies, ASTRO
12 or ACRO, as well.

13 CHAIRMAN MALMUD: Thank you. Oh, here, a
14 member of the public.

15 MR. WHITE: Gerald White with the AAPM.
16 AAPM has previously commented to your organization and
17 to the ACMUI about the inappropriateness of placing
18 the burden of solving this problem upon patients and
19 medical institutions, when the problem is really
20 primarily that of the security staff who fail to
21 adequately identify, as you seem to have solved, which
22 patients have medical isotopes and which don't.

23 So I have two questions. One is formal
24 and one is perhaps a bit more informal.

25 The first is, Do you plan to study the

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1 feasibility of the ability of security
2 forces to identify these isotopes, using
3 commonly available spectroscopic instruments that are
4 field grade, and the second question is there was a
5 lot of discussion about the type of forms one might
6 carry going into the Super Bowl, was it? some sporting
7 event, post-medical procedure. How does a security
8 person distinguish between a patient having a thallium
9 scan with one of these cards from a hospital and a
10 ne'er-do-well terrorist with dirty bomb material,
11 carrying the same letter from Kinko's, from a
12 hospital?

13 DR. ANSARI: The first question, the
14 answer is no, we don't have any plans to do that.
15 It's sort of I think outside the--I think there are
16 other agencies who are addressing that topic and I
17 think it could be done. I don't necessarily agree
18 with you. And I also agree with you on the second
19 point that you raise, that that would always be an
20 issue. You always have to, for any counterfeit
21 documentation that's produced, that will always be an
22 issue. I agree with you.

23 The other thing that I'd like to say is
24 that even though the law enforcement should try with
25 better use of their existing instrumentation, or by

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1 improving their instrumentation, to say that it's not
2 mutually exclusive to do that and also to better
3 inform the patient. Because I think some of the
4 comments that came from AAPM, was, if I remember
5 correctly, said that, it was something like they don't
6 want to burden the patient with information.

7 We tend to look at it differently. We
8 think a better-informed patient is a better thing. We
9 don't think about burdening the--we don't look at it
10 as burdening the patient with information.

11 CHAIRMAN MALMUD: Dr. Eggli.

12 MEMBER EGGLI: I would agree with your
13 final statement, which was sort of the point I was
14 going to make. In my practice, I tell every therapy
15 patient, I need to think about telling diagnostic
16 patients too--and what I tell them is this is no joke.
17 They will treat you like terrorist and it will be
18 unpleasant.

19 And I think the issue is to get patients
20 to follow the restrictions. One of the things that
21 will be helpful to the community practitioners is to
22 understand how long specific isotopes are likely to be
23 detected and what's a reasonable guideline.

24 I can give a patient 150 millicuries of
25 radioactive iodine and release them because of the

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1 exposures, but they are athyreotic and they will have
2 it in their system for three or four days, and it'll
3 be, it'll get fairly low level fairly quickly.

4 Likewise, I can give a hyperthyroid
5 patient 15 millicuries of iodine, 10 percent, and
6 that'll be in their system a whole lot longer cause
7 their thyroid's going to hang on to that. So some
8 practical guidance for practitioners on the
9 recommendations that we should give patients with
10 respect to duration of avoidance. I tell them avoid
11 airports, avoid public transportation, avoid
12 government buildings. Some guidance on also what
13 should be avoided, and how long it should be avoided,
14 would be very helpful.

15 MR. WHITE: Just to correct the record,
16 AAPM did not object to burdening the patient with
17 information. What we objected to was requiring the
18 responsibility of the patient to educate security
19 personnel on their medical condition. That was the
20 objection we had. It was different than information
21 to the patient.

22 CHAIRMAN MALMUD: Dr. Katz.

23 DR. KATZ: I actually have a comment
24 about, sir, your last question. That was specifically
25 asked, had a question on the questionnaire, How can

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1 the respondent distinguish between a bona fide patient
2 and a terrorist?, and apparently these cards include
3 a phone number to call, and if the person who is on
4 the other end of the phone is somebody who has access
5 to the medical records and can check whether that name
6 actually--I mean, perhaps it's still a system that can
7 be broken, but there is some--

8 MR. WHITE: You should understand that a
9 phone call to a hospital requesting information about
10 a patient's medical treatment cannot be answered in
11 the absence of a previously-signed release for that
12 information.

13 If someone calls our hospital making that
14 request, our people are forbidden to respond.

15 MEMBER EGGLI: Yes. This is a HIPAA
16 issue. If a Border Patrol agent calls our hospital in
17 the middle of the night and asks for information on a
18 patient record, if I release that information to a
19 Border Patrol agent, I'm violating a different federal
20 law, which is called the Health Insurance Portability
21 and Accountability Act. I cannot release that
22 information.

23 I can put my phone number on a card, but
24 it doesn't matter, because I can't release the
25 information, unless I have specific written consent

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1 from the patient to do so.

2 MEMBER NAG: Could I address your point?
3 You know, when we have an authorization from the
4 patient that allows us to release that information and
5 technically, the phone number we gave was not the
6 phone number of the doctor because he may not be
7 available, and we give the phone number of the
8 admitting supervisor who has the list of, you know,
9 all patients, that they can at least--not know how
10 many millicuries he was given, but they can say that
11 this patient as a patient who had a prostate implant
12 on such and such a date.

13 CHAIRMAN MALMUD: Dr. Schwarz.

14 MEMBER SCHWARZ: And I think, I'm not sure
15 that we actually have signed sheets at Washington
16 University, but certainly if we do something in
17 combination with the Society of Nuclear Medicine or
18 one of the oncology societies, too, that could be part
19 of what you put in place, that they do sign the
20 document that essentially allows information to be
21 released when they get the card from the physician.

22 CHAIRMAN MALMUD: Dr. Fisher.

23 MEMBER FISHER: Just one more point of
24 clarification. If the activity detected is internal
25 to the patient, that's not of concern to the border

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1 inspection people. That's not what they're looking
2 for. They recognize that that's most likely related
3 to a medical diagnosis or therapy. What they're
4 looking for is suspect radioactive material and cargo
5 that meets certain definitions. but they're not
6 really interested in what isotope did you get. In
7 fact they have very much difficulty identifying very
8 low energy Auger emitters, palladium, iodine-125,
9 cesium-131, because it's below the spectroscopic
10 threshold of sodium iodide systems.

11 But they're not really interested in the
12 isotope. They recognize it's a medical patient. What
13 they're looking for is items in cargo.

14 DR. KATZ: Dr. Fisher, is it true to say
15 that the experience is limited to Border Patrol,
16 because there's clearly, you know, there's people who
17 set them off who are at garbage dumps, you know,
18 tunnels. So it seems like there is a group of people
19 who are really well-trained but are there law
20 enforcement personnel who are well-trained, outside of
21 the Border Patrol areas?

22 MEMBER FISHER: I can't speak to that.

23 DR. KATZ: But your experience is about
24 the border control; right?

25 MEMBER FISHER: Airports. Ports of entry.

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1 DR. KATZ: Okay.

2 MEMBER GILLEY: But TSA is not U.S.

3 Customs.

4 MEMBER FISHER: No. TSA is a separate
5 agency, a part of Homeland Security.

6 CHAIRMAN MALMUD: Dr. Suleiman.

7 MEMBER SULEIMAN: Yes. It's sort of a
8 hodge-podge--I mean, some of our FDA inspectors in the
9 field, because some of the products coming in have to
10 clear Customs also, so some of them do have radiation
11 detectors, and a lot of first responders, and
12 whatever, and in some cases, a lot of these people are
13 trained to detect the radiation but then they call in
14 more expert people to help analyze and figure, but
15 it's--you've got a whole multitude of agencies working
16 at these things on different levels. There's not a
17 simple--

18 CHAIRMAN MALMUD: Other comment from the
19 public?

20 MR. PETERS: Yes. This is Mike Peters,
21 SNM, just coming to answer Dr. Ansari's call for
22 comment.

23 As you probably know, and you saw the
24 American College of Nuclear Physicians slide, that
25 showed a Web site article from 2003, SNM also had that

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1 same exact article on our Web site, that we've had,
2 actually, for the past five years, and we recently
3 updated it last holiday season, as they said, with a
4 press release, and it was well-accepted by the
5 international trades as well as the normal press, and
6 we feel an ownership over this issue, and that's why
7 we've offered to help the CDC communicate with our
8 community and our membership, and we're looking to do
9 that.

10 We obviously have JNM, we have our press
11 group, our communications team who can release press
12 releases about this, and this is again an issue that
13 we feel is our issue and we're really looking forward
14 to working with the CDC to educate the community about
15 this. That's all I have to say.

16 CHAIRMAN MALMUD: More comment from the
17 public?

18 MS. FAIROBENT: Lynne Fairobent with AAPM.
19 Just one thing I would like to caution, sitting here
20 listening to the discussion. I think the cards, I
21 think the outreach are great, but don't let anybody
22 misbelieve that providing a card to somebody with a
23 phone number, that they call back to a facility that
24 verifies whatever name is asked of them, is anything
25 to assure that that is a valid receptor call.

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1 Terrorism organizations are very well
2 adept at setting up this sort of a system. There is
3 no verification that the number for the facility
4 provided is a legal or valid facility, without any
5 other documentation than a voice message on the other
6 end of the phone.

7 CHAIRMAN MALMUD: Thank you very much.

8 MS. WASTLER: I believe Dr. Ansari has a
9 second presentation as well.

10 DR. ANSARI: Yes. That one should be a
11 shorter one, much shorter one.

12 CHAIRMAN MALMUD: We'll give you time to
13 prepare it. Are you ready? Okay.

14 DR. ANSARI: Okay. This is now a major
15 shift from minuscule doses and issues of convenience,
16 and patient education, to some issues that are
17 potentially life-saving situations and emergency
18 response issues to nuclear radiological terrorism
19 incidents.

20 This is a topic that I'm not sure that--I
21 appreciate you giving me the time to share it with
22 you. I'm not sure if it's a topic that this committee
23 may or may not want to address directly, but since I
24 was coming here for the other study, I asked for a few
25 minutes to share this with you.

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1 Again, anything stupid is just me, not
2 CDC. Here's the issue. That availability of the
3 medical community would be heavily involved in
4 response to a nuclear radiological incident, and the
5 hospital in-house radiation expertise. This is the
6 radiation safety officers, may be physicists, nuclear
7 medical technologist, will be the invaluable asset.
8 This is considering that we have the human resource
9 issues, specifically health physics support, radiation
10 safety issued support at all levels of response.

11 This is really significant, and in our
12 outreach to the hospitals in the training material
13 that we prepare for emergency response for clinicians,
14 emergency department clinicians, we stress to them to
15 utilize their in-house staff of radiation scientists,
16 technologists, to assist them in their emergency
17 planning. So we stress this to them.

18 We think that RSOs, medical physicists and
19 nuclear medicine technologists should be included in
20 the hospital emergency response plan, should be
21 familiar with their roles, what will be expected of
22 them in such an emergency and they should be engaged
23 before an incident occurs, to be most effective when
24 it does.

25 We've done some focus group research with

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1 emergency department clinicians, and these are the top
2 concerns that they have expressed to us, that their
3 hospital would be overrun. Actually, you're all
4 familiar with these concerns, safety of their loved
5 ones, lack of adequate staffing, preparedness,
6 contamination of their facilities and self-protection.

7 And one thing that we told them is that
8 their in-house expertise can address many of these
9 concerns that they have, if they use them effectively
10 in their planning.

11 If we look at the hospital incident
12 command system, and there are some internal scenarios
13 like bomb threats, hostage crisis, loss of power.
14 There's some external scenarios that actually match
15 the national planning scenarios, that includes nuclear
16 detonation and RDDs.

17 And looking at the incident command flow
18 chart, the structure, and the candidate positions for
19 these command positions, for the radiation safety
20 officer position, right here--there is another slide
21 I didn't show--the radiation safety officer, the
22 candidate position is specifically listed in the HICS
23 as a radiation safety officer, with the primary duty
24 of assessing the--to do a situational assessment and
25 identifying issues of concern, and addressing them,

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1 and responding to the incident commander, working
2 directly with him.

3 The other position, medical technical
4 specialists, specifically listed as potential
5 candidates for this position of radiation safety
6 officer are medical physicists and nuclear medicine.

7 And people that serve in this position
8 have numerous roles. One of them is rumor control.
9 This is rumor among the staff, making sure that the
10 hospital staff get proper information, because if they
11 don't, and the rumors spread, then the whole hospital
12 response is going to get messed up.

13 So this is a very critical position, and
14 for radiation scenarios, emergency response scenarios,
15 this is what's actually right now listed in the
16 hospitals, in the command system.

17 We have key roles in planning, training.
18 In planning, just drafting, reviewing job action
19 sheets. They need to be involved in doing that. They
20 need to be involved in training, they need to be
21 involved in exercises, and when it comes to the
22 response, they would have input in the received
23 treatment of patients, protection of care providers,
24 providing screening for patients. This is for not
25 only just external, like screening for internal

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1 contamination, and also providing assistance in
2 producing communication material, and many more
3 functions.

4 And the question is that is the hospital
5 emergency staff prepared to take on those roles? They
6 have a certain familiarity with HICS. They need some
7 familiarity with the relevant state and federal
8 guidance documents. They also need to be familiar
9 with the training material for clinicians.

10 The reason for that is that if they're
11 familiar with the training material for clinicians,
12 for radiation emergency response, they can anticipate
13 what type of issues they may be asked to provide input
14 for, what kind of assistance do we ask of them. They
15 can at least be prepared for that.

16 Those are the type of technical
17 consultations they might have to provide, not only the
18 health and safety of the staff, interpretation of the
19 guidance documents, dispelling rumors, screening
20 criteria. This is the hospital staff, the radiation
21 staff could really help their clinician colleagues in
22 doing their job.

23 Sometimes they just need to function as
24 translators, technical liaisons. And the good news is
25 that the hospital radiation staff are highly-qualified

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1 radiation professionals. They are highly-skilled
2 professionals, they have a great interest in homeland
3 security issues, we know that, and, for example, when
4 the Nuclear Radiation Society tries to fill
5 committees, there is no problem filling homeland
6 security committees because there's no much interest
7 in that.

8 And the specialized training that it
9 requires is really minimum, because you don't--there's
10 so much of it is radiation experts. So we just have
11 to acquire very minimum emergency response training.
12 And the problem is with some of the feedback that we
13 have, is that the people we talk to feel they may not
14 have the support from management, the management
15 doesn't engage them in emergency response planning,
16 and if they want to go and get the specialized
17 training, they felt that if hospital management
18 supported them more, if there was some, this training
19 became a recommendation, or a requirement or
20 recommendation, they could use that as an incentive to
21 get their management to support them better.

22 So this is the feedback that we had, and
23 the reason I wanted to--I knew that you were looking
24 at training requirements, and so forth, in an entirely
25 different context, but I just thought I'd share this

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1 with you, that this is also an emergency response
2 function, it doesn't have to do with license
3 procedures but it's a real issue, and this is
4 something we're going around the country telling
5 clinicians and hospitals, to use radiation experts,
6 but we do feel that those radiation experts themselves
7 feel they need a little bit of extra training and
8 support from the management.

9 CHAIRMAN MALMUD: Any questions or
10 comments.

11 Dr. Welsh.

12 MEMBER WELSH: I think your presentation
13 or overview was excellent; however, it did not include
14 radiation oncology as one of the technical and medical
15 specialists, and I feel strongly that where radiation
16 oncology is available, understanding that many
17 facilities don't have that, the radiation oncology
18 physician is perhaps the one most familiar with
19 radiation-related injuries and could be an invaluable
20 member of this team.

21 And I strongly recommend that, where
22 available, radiation oncology either lead that
23 program, or be integrally involved in it.

24 DR. ANSARI: Thank you. Yes, definitely.
25 This angle was formally health physics type of the--

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1 but absolutely, yes. Thank you.

2 CHAIRMAN MALMUD: Dr. Nag.

3 MEMBER NAG: Yes. In that same regard,
4 ASCO is the national organization for radiation
5 oncology and that that had radiation oncologists for,
6 you know, similar incidents.

7 CHAIRMAN MALMUD: Most hospitals today do
8 have programs in preparation for biologic, chemical
9 and nuclear terrorism, or events. Sometimes they're
10 simply events, a chemical plants explodes, etcetera,
11 etcetera.

12 And the first thing a hospital does in a
13 situation like this, with multiple potential injuries,
14 is to slam the door shut to the entire hospital. The
15 entire hospital has to shut down, no access, no
16 egress, except through the emergency department, and
17 the emergency department has to be separated itself,
18 from the outside, with a system of tents, which are
19 usually used to decontaminate, to undress the patient,
20 decontaminate with fresh water, and then redress the
21 patient, and then allow the patient, who's no longer
22 contaminated, whether it's biological, chemical or
23 nuclear, into the hospital. But not until then.

24 And having run a few hospitals for a
25 while, when we had two situations, the first thing we

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1 did was close the doors. I locked the doors of the
2 hospital. Otherwise, the hospital gets flooded with
3 people who come in and contaminate the hospital,
4 potentially contaminate the hospital.

5 Most hospitals are waiting for federal
6 funds in order to underwrite this effort, and while it
7 is an issue of first responders, the community's first
8 responders, and the hospital, they all seem to be
9 sitting, waiting for federal funds to come through in
10 order to underwrite this effort. And it's
11 understandable considering the strapped funds that
12 most hospitals in major urban centers face.

13 But we agree that this is an issue in
14 which our radiation safety people should be intimately
15 involved, and our hospital, which is the leading
16 trauma center in Philadelphia, the leading penetrating
17 trauma center in Pennsylvania, does have a plan, has
18 instituted it through radiation safety, in fact, and
19 we have been respirator-trained as well, those of us
20 who wish to volunteer.

21 But I've watched the process from a
22 distance now, and it's quite clear to me that there
23 will not be an adequate response, which must be a
24 local response, until there's federal funding for it,
25 not diverted to some other purposes, and that is a

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1 political issue which we don't have to deal with but
2 we do appreciate your bringing this to our attention.

3 I'm certain that most radiation safety
4 officers are already aware of the issue and their need
5 to participate, are they not?

6 Dr. Williamson?

7 MEMBER WILLIAMSON: Yes.

8 [Laughter]

9 MEMBER LIETO: I had a question.

10 CHAIRMAN MALMUD: Mr. Lieto.

11 MEMBER LIETO: Does CDC provide training
12 for hospitals, medical physicists and health
13 physicists?

14 MEMBER GILLEY: Yes.

15 DR. ANSARI: Training for clinicians or
16 for--

17 MEMBER GILLEY: Yes.

18 MEMBER LIETO: I know they have for
19 clinicians. I'm talking about like the health
20 physicist, or a hospital are, so non-physician are, so
21 medical physicists.

22 MS. WASTLER: Yes. There's a REACTS
23 course that you can take.

24 MEMBER LIETO: Well, REACTS is in--

25 MS. WASTLER: Oak Ridge, Tennessee.

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1 DR. ANSARI: REACTS. This is for
2 radiation emergency--

3 MS. WASTLER: Medical personnel.

4 DR. ANSARI: Yes. The training is geared
5 for a medical type of response. They have two forms.
6 They have two levels of training. Both of them are
7 already medical-oriented. But the type of training I
8 don't think REACTS, addresses this type of training
9 we're talking about, preparing the radiation, health
10 physics support community in the hospital, preparing
11 it for response, how they would be--there is no such
12 training, to my knowledge. We have identified this at
13 CDC as a target audience.

14 So, in fact, if there are partners that
15 you can identify, that we could work with to develop
16 such training material, this is on our, actually,
17 radar right now, and identified as a need.

18 MEMBER LIETO: Thank you.

19 CHAIRMAN MALMUD: Member of the public.

20 MS. ROMANELLI: I'm Gloria Romanelli,
21 American College of Radiology. Despite the fact that
22 I don't want to be a "me too" organization,
23 radiologists are also a key component to educating the
24 public, and physicists who do not happen to be RSOs
25 are also going to be very valuable.

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1 The ACR, AAPM, and ASTRO, several years
2 ago, put together a disaster preparedness primer for
3 medical professionals, that essentially deals with the
4 key components that those individuals might have to
5 deal with in the event of a radiological dispersal
6 device disaster, and that document is available and
7 we'd be happy to share it with anybody who would like
8 a copy.

9 DR. ANSARI: Actually, a very well-done
10 document and in our outreach we always reference that.

11 MS. ROMANELLI: Right; right.

12 CHAIRMAN MALMUD: Thank you for bringing
13 that to our attention. There is a rich literature on
14 biological, chemical and nuclear terrorism. Something
15 worth reading, if you have the time, is Dark Winter,
16 which was a product of the Federal Government, it must
17 be five years ago, which was a scenario of what would
18 happen if there were a biologic event in the United
19 States.

20 And then there are other documents which
21 are mimics of other events. They're available on the
22 Internet. They're federal documents. I suggest that
23 you read them while you're not around your children,
24 because you don't want them to read this as well.
25 It's a very upsetting document, in which the federal

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1 officers role-play other federal officers, and
2 demonstrated our ability to respond to a major
3 catastrophe.

4 Yes, Dr. Suleiman.

5 MEMBER SULEIMAN: Yes. I think one
6 resource I hate to pass without mentioning is AFRRRI,
7 the Armed Forces Radiobiology Research Institute.
8 They actually have quite a bit of good, useful
9 documents on their Web site. I don't have their Web
10 site memorized, but they're in Bethesda. But they've
11 been doing this sort of thing for years.

12 CHAIRMAN MALMUD: Thank you. Oh, I'm
13 sorry. Excuse me.

14 MEMBER THOMADSEN: REACTS does have a
15 course for these people, not the physicians, and they
16 recently brought a shortened version of it to
17 Wisconsin, where they took it to several places in
18 Wisconsin and put it on for local medical physicists,
19 health physicists, and persons like that. So you can
20 arrange to have it more locally.

21 DR. ANSARI: While we're going over
22 resources, one other thing I'd like to mention is the
23 REMM Web site that Department of Health and Human
24 Services had recently--it went online in March. It's
25 R-E-M-M, and if you type that, if you Google that with

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1 National Library of Medicine, then the first entry
2 will come up, actually, on their Web site. It's
3 Radiation Event Medical Management, R-E-M-M. It's
4 really rich with lots and lots of information.

5 MS. WASTLER: A very good site.

6 DR. ANSARI: Sorry?

7 MS. WASTLER: I said it's a very good
8 site; very informational.

9 DR. ANSARI: Yes. It is also
10 downloadable, so you can actually hit download and
11 download everything on your desk top, so you don't
12 have to have Internet connection to use it.

13 I just wanted to mention that. I do want
14 to mention one example of the kind of training and
15 education that I'm talking about, that is not covered
16 by any of these resources. I will give you one
17 example.

18 Screening for internal contamination. The
19 guidelines are you look at the ALI. For example, if
20 the decision is based on this number, based on this
21 number of patients, it will treat, for adults,
22 anything above 5 ALI of intake. And then they're
23 going to use the thyroid optic scanners and screen
24 patients at this distance to basically screen them
25 out.

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1 People we need to talk to are these
2 radiation physicists, medical physicists, nuclear
3 technologists, who not only understand ALI, and they
4 also operate those machines and can read the
5 instructions, and knew exactly what to do, cause
6 they've done it before.

7 And this is the kind of thing that is not,
8 right now, available. This is the kind of thing that
9 we would be happy to prepare training material, and
10 then provide that, and so this specialized training
11 that I was talking about is this type of information
12 that's currently not available.

13 It's the kind of issues that you need the
14 best people in the hospital to address it, would be
15 this group. That's it.

16 CHAIRMAN MALMUD: Thank you, Dr. Ansari.
17 Any other comments?

18 [No response]

19 CHAIRMAN MALMUD: If not, I guess we need
20 to move on to the next agenda item.

21 MS. WASTLER: Right. While we're
22 switching speakers, I'd like to--one of the last
23 questions that came up before we broke was to discuss
24 how we can basically make up some time on the
25 schedule. During lunch, I went back and reviewed the

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1 schedule, and the last three items, the Elekta
2 Perfexion, the AU approval for byproduct material by
3 Dr. Welsh, and the NMED are three--well, the first two
4 are informational, and my recommendation is that we
5 basically we will hold those over to the next meeting.
6 It's not necessary that they be discussed today.

7 The NMED presentation is also something
8 that I'm going to recommend that we move over until
9 the next meeting. This was issues that were raised by
10 Mr. Lieto, and Michelle Burgess, who is my project
11 manager on NMED, has met and had several discussions
12 with him, and has answered his questions, and what we
13 were proposing to do is just share that information
14 with the full committee.

15 So from the full committee's perspective
16 it's informational. So by eliminating--or not
17 eliminating--but postponing those three discussions to
18 the next meeting, it will free us up and we'll be able
19 to make up the time. So I wanted to put that forward
20 and make sure that that was agreeable to everyone.

21 MR. REED: Could you restate the agenda
22 items. I didn't hear the numbers.

23 MS. WASTER: Item number 17, 18. What's
24 the matter? You can't hear? Oh, the comment from the
25 gentleman in the audience. Sorry, Donna-Beth. I

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1 didn't get a chance to get back to you on that; but
2 yes.

3 So if that's agreeable to everyone, we'll
4 postpone 17, 18, and 19 and move them to the next
5 agenda, they're informational, and that will allow us
6 time to complete 14, 15 and 16, and the closing within
7 the allotted time.

8 MEMBER NAG: You know, I think something
9 longer than that, it still wouldn't fit in.

10 CHAIRMAN MALMUD: We've already taken time
11 for lunch, so--

12 MS. WASTLER: We've shortened the lunch
13 hour, so I think we've gotten--

14 MEMBER NAG: Are we going to eliminate the
15 break also?

16 MS. WASTLER: No.

17 CHAIRMAN MALMUD: No. It's 2:15 now, it's
18 two hours, so that's 4:15, fifteen minutes to close.
19 We're okay.

20 MS. WASTLER: Right. And I would point
21 out that I discussed with Dr. Eggli, the timing, and
22 he feels that the sentinel lymph node can be done in
23 a shorter period of time. So I think those three,
24 postponing those--you know, you never know how
25 discussions are going to go, but I think that's a

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1 reasonable--at least those are things we can move, and
2 we know, because they're informational at this point.
3 We may have to make other adjustments. So that's my
4 proposal.

5 If that's all right with you, Mr.
6 Chairman, that's what we'll do.

7 CHAIRMAN MALMUD: It is; thank you. You
8 cleared this before, so we're happy.

9 MS. WASTLER: Okay.

10 CHAIRMAN MALMUD: And therefore the next
11 item is novel radiotherapeutics with Dr. Suleiman.

12 MEMBER SULEIMAN: Thank you. I'll try to
13 circle this relatively smoothly. Even though the
14 opinions expressed are those of--they're mine, and not
15 necessarily an official endorsement or criticism by
16 the department, Public Health Service or FDA, I don't
17 think I'll make any intentional effort to bypass FDA
18 policy. It's just that we are a pretty large
19 regulatory agency, and sometimes we have different
20 laws, and a whole variety of different regulations,
21 and constantly changing policy.

22 So I'll try to best reflect that.

23 This will differ, just a little bit, from
24 the handout, but basically, this is a question that's
25 been bothering me for the last few years.

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1 I come from a broad background, and I've
2 only gotten involved with some of these therapeutics
3 in the last few years.

4 The thespheres are medical devices, as
5 Donna-Beth keeps on reminding me, but they're used as
6 radiotherapy. The Bexxar and the Zevalin are
7 monoclonal antibodies recently approved in the last
8 few years, by FDA, actually, by the Center For
9 Biologics.

10 They go after non-Hodgkin's lymphoma. One
11 used an imaging agent, I-131, but delivers the dose
12 with I-131. Zevalin uses indium-111 as the imaging
13 agent but also delivers a dose of it with yttrium.

14 And there's some other therapeutics that
15 have been out there for a while, and I-131 is sort of
16 the decades-old classic. But even talking with a
17 number of colleagues, I said how accurate is the
18 dosimetry, or what are these therapies used for. It's
19 obvious that they're basically used for, radiotherapy
20 is basically used for refractory patients or late-
21 stage disease, and so the state of the practice in
22 terms of the dosimetry for these products is not as
23 good as it is for some of the other dosimetry
24 requirements.

25 Very briefly, and I'll discuss this a

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1 little bit later too, but we have a lot of confusion
2 out there.

3 I'm involved with a program where we
4 require people to report doses and activities to us,
5 and it just fascinates us, how inconsistent people are
6 in terms of reporting dose. Administered activity
7 clearly is a function of the calibration accuracy, and
8 when I think of calibration, I always think of NIST
9 traceability.

10 There is accuracy at the manufacturer and
11 there's also validation or independent verification by
12 the user. NIST does not always involved--NIST, the
13 National Institute of Standards of Technologies--name
14 is thrown around a lot.

15 I had the opportunity, recently, to talk
16 with some of the people at NIST, and they're involved
17 with some, and they're clearly not involved with
18 others. So all sources are not traceable to NIST.

19 Radiation-absorbed dose, as most of the
20 people here in this room know, is very much dependent
21 on a variety of things in terms of how much activity's
22 administered to the subject, to the patient, the
23 pharmacokinetics or biodistribution, not only within
24 the body but within specific tissue, and if you're
25 thinking of therapy, you're thinking of what's the

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1 target volume.

2 Also we all deal with risk, and so that
3 gives us a little bit of latitude, in that if we talk
4 about diagnostics, the risk really is the
5 probabalistic, the chance of developing a cancer many
6 years down the line, if at all. They're considered to
7 be relatively safe. The uncertainty in dose
8 estimation for diagnostics are very high, clearly,
9 less than one significant figure but acceptable in
10 practice.

11 When you get into therapeutics, and I'm
12 not really sure if I've slighted anybody here, but my
13 perception has always been that external beam therapy
14 probably has very, very good precision and accuracy in
15 terms of delivering radiation-absorbed dose to a
16 target volume. I get a sense that brachytherapy isn't
17 far behind but I've had to defer to my colleagues to
18 tell me how accurate I am.

19 But I think I lump external beam and
20 brachytherapy together, when you talk about internal
21 lung sealed sources or brachytherapy devices, meaning
22 the microspheres, the doses--and I use that term
23 loosely--delivered, are probably acceptable for the
24 clinical indications that they've been approved for
25 and used, but these are not first-line therapies.

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1 They're used for patients for which other therapies
2 have failed. They're used for palliative purposes or
3 they're used for humanitarian purposes.

4 I just threw these pictures in there to
5 make the talk a little interesting, but when you talk
6 about internal dosimetry, you talk about the old MIRD,
7 Medical Internal Radiation Dosimetry, and this is the
8 model that's been around for decades, and recently,
9 there's a lot of exciting research, I'm not going to
10 go into that, but you're seeing much more realistic,
11 you know, models developed.

12 This is some work done at the University
13 of Florida, and they're not the only institution doing
14 research along this line. But you're seeing much more
15 a set of realistic models for calculating dose.

16 The point I want to make here is that if
17 you look at the axial image on the left of the
18 mathematical, the old MIRD model, and the axial image
19 to the realistic, it's obvious that organ geometries,
20 and whatever, would clearly impact on dose.

21 And this is a little bit more dramatic.
22 Here's your mathematical liver and your mathematical
23 stomach, and you see how different they are, in fact,
24 from a more realistic liver and stomach.

25 But the point I'm making here is depending

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1 on which mode you use, and we've got three of the Oak
2 Ridge models, these are, I think, the Christie
3 pediatric phantoms and these are three of the
4 University of Florida pediatric models.

5 The doses can be off by orders of several
6 factors and how these relate to reality is also, you
7 know, highly questionable in terms of the actual
8 patient. Obviously for therapeutic, you actually do
9 deal with patient specificity, but I'm concerned that
10 a lot of people, in terms of some of the nuclear
11 medicine type applications, may be applying diagnostic
12 methodology and not appreciating the therapeutic
13 needs.

14 This is an area that is so fundamentally
15 simple, that I'm just fascinated, why there's so much
16 confusion out there. But when you talk about
17 administered dose, we're talking about activity, but
18 is it the mass dose, the pharmacologic dose, and is it
19 radioactivity? We still have, you know, a strong body
20 of people out there who think millicuries.

21 Radiation-absorbed dose, we all learned
22 this, and it's pretty straightforward, it's really a
23 physical quantity, a 100 ergs per gram or joule per
24 kilogram, and equivalent dose, we've sort of looked
25 the other way over the years, because most medical

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1 radiation, be it gamma, x-ray, electrons, have a
2 quality factor of what's now known as radiation
3 weighting factor of about one. So the term rads and
4 rems, or grays and sieverts, are used extremely
5 interchangeably.

6 I'm invoking a little bit of science here
7 but there's some real fascinating research out there
8 that's going to change this whole concept, in that
9 we're going to have to pay a whole lot more attention
10 to the actual equivalent dose.

11 There were some papers, recently--the work
12 by George Saguros up at Hopkins, where he's been able
13 to demonstrate, very exquisitely, that the radiation-
14 absorbed dose, same physical-absorbed dose, but can
15 demonstrate a dose rate effect just to tissue.

16 So, clearly, for particulate for
17 electrons, and there are some alpha emitters, that are
18 trials in Europe, where, clearly, the equivalent dose
19 is going to be very dramatically different than the
20 radiation-absorbed dose.

21 So what I'm getting at here is if
22 therapeutics are eventually going to develop into a
23 first-line therapy, then the dosimetry, in terms of
24 determining the administered activity, be it NIST
25 traceable, or some way that you can actually

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1 standardize this activity, and how the absorbed dose
2 to the patient is calculated is really going to have
3 to improve over the current state of the practice.
4 Clearly, standard reference models are not going to be
5 acceptable, but they're a good first step in
6 approximating the dose.

7 In addition to absorbed dose, as I said,
8 the concept of equivalent dose I believe is going to
9 have to come into much better use, because I think
10 it's a much more accurate descriptor. I had, as I
11 said, in preparation for this over the last two years,
12 it was an idea that's been in my mind, I've talked to
13 therapists, I've talked to people from all
14 backgrounds, and I've been surprised, basically for
15 thyroid ablation, most people will give a set
16 administered activity.

17 There was a presentation last week, where
18 the physician said we give 150 millicuries. Now most
19 of the people at this table represent the cream, and
20 so you're not necessarily representative of what's
21 going out there in practice, but I have a hunch that
22 a lot of these therapeutics, the dosimetry is
23 questionable at best. It does what it intends to do.

24 Tissue modifying factors, and I think I'm
25 going to--that term I got from Saguros and his

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1 presentation, where he's showing dose rate effects,
2 and clearly, how you define relative biological
3 effectiveness will become much, much more critical for
4 radiotherapeutics in the future.

5 And the area that maybe we could have more
6 impact, or at least awareness, is that doses are not
7 always directly and independently verified or
8 verifiable, and manufacturers make an effort, but
9 sometimes, in some cases, the user has to trust what
10 they have.

11 So why discuss now? My perception is that
12 the state of the practice needs improvement and I
13 think that the success and acceptance of some of these
14 radiolabeled medical products, either in clinical
15 trials or in clinical practice, and the ultimate
16 efficacy of this class of radiotherapeutics, is going
17 to have to depend on application of better science, be
18 it radiobiology and some of the dosimetry.

19 So I just raise this to the committee and
20 if everybody thinks I'm wrong, say Orhan, we've got
21 this under control, we can deliver dose with this
22 accuracy. Another presentation last week at the SNM
23 basically demonstrated that if you knew the actual
24 dose that was being delivered to patients, it actually
25 improved outcome.

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1 That's not a surprise but it's been a
2 revelation to me, that basically, with
3 radiotherapeutics, I don't think the level of
4 precision and accuracy and dosimetry is anywhere near
5 comparable to what exists with external beam and
6 brachytherapy.

7 And I want to thank Wes Bolch for using
8 some of his slides for the phantoms and the Agency for
9 paying my salary.

10 CHAIRMAN MALMUD: Thank you. Yes, Dr.
11 Nag.

12 MEMBER NAG: DR. Suleiman, I couldn't
13 agree with you more. There are many of these where
14 not sufficient dosimetry work has been done yet.
15 However, for example, if they're microsphere with the
16 AEM, we have formed a task force. The first one was
17 to get a clinical guideline and now we are having a
18 task force for dosimetry. Similarly, for many of the
19 other new modalities, more work needs to be done in
20 the dosimetry aspect, and I fully support you.

21 MEMBER SULEIMAN: Let me make a statement.
22 This is my own opinion. I think there's a real
23 potential for a very effective product here, and I'm
24 afraid, you know, some of these products may not even
25 clear clinical trials if the science isn't applied to

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1 the way these things are conducted.

2 MEMBER EGGLI: I think the microspheres
3 are unique in that you have more control over the
4 distribution and therefore you can calculate the dose.
5 In many of these unsealed systems, the biodistribution
6 changes from patient to patient.

7 The MIRD equations that can be used to
8 calculate the dosimetry make assumptions big enough to
9 drive a Mack truck through and the small differences
10 in quality factor between a beta particle and a gamma
11 ray are totally lost in the assumptions of the MIRD
12 equations.

13 The other thing to note is the benefit of
14 the dosimetry attempt, in some cases is quite small.
15 In high dose therapies, we try to do dosimetry, at
16 least we try to predict the maximum safe exposure that
17 we can give the patient's bone marrow, and try to
18 maximize the amount of radiation that gets into the
19 tumor.

20 In most of the cases, particularly post-
21 thyroidectomy, the uptake is very low, so the amount
22 of radiation you're delivering is actually fairly low
23 to the volume, if you look at retained radiation
24 iodine. In many of our goals in therapeutic iodine,
25 which I'll have to disagree and say iodine is a

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1 primary therapy in many diseases and it is not a
2 salvage therapy, it is the primary therapy for most
3 thyroid disease, and it's a first-line therapy and
4 it's been a first-line therapy for more than 50 years,
5 and the fact that our cure rate in thyroid cancer is
6 in excess of 95 percent, says that the therapy is
7 quite effective.

8 MEMBER SULEIMAN: No; no. I consider I-
9 131 therapy as primary.

10 MEMBER EGGLI: Okay. But the issue is in
11 cases where you cannot reliable predict a
12 biodistribution, then you have to have some kind of a
13 dosimetry experiment, and very sophisticated models
14 that allow you to measure the biodistribution at
15 dosimetry, and then I can tell you, a 100 percent for
16 sure, based on looking at whole body disappearance of
17 radioactive iodine, that what you did at dosimetry may
18 bear absolutely no relationship to the biodistribution
19 that occurs when you do your therapy, and that's a
20 huge problem in trying to apply some of these
21 dosimetric techniques to these unsealed sources
22 delivered internally.

23 CHAIRMAN MALMUD: Dr. Williamson. Then a
24 member of the public.

25 MEMBER WILLIAMSON: Yes. I just wanted to

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1 simplify one point. I agree fully, with both
2 speakers. I think there is, in theory, in principle,
3 you know, the possibility of great gains by improving
4 the therapeutic ratio through dosimetry but the
5 challenges are formidable and sometimes escape, defy
6 solution, even in principle.

7 Another area of uncertainty is target
8 volume delineation and determining the pattern of
9 uptake within an organ and what constitutes the target
10 you're trying to treat. This is, you know, also, in
11 many cases, a factor of two uncertainty, if you were
12 to look. I would also decouple, completely, the
13 concept of effective equivalent dose, which is a
14 radiation protection concept that I think is intended
15 to be a predictor of carcinogenesis for every low-
16 level exposures, from the more sophisticated
17 radiobiological and outcome models that are needed to
18 predict therapeutic response, and I think it's very
19 clear from the experience in radiation therapy, that
20 the kind and nature of model that you need is highly
21 dependent upon the target organ, the critical tissue
22 being irradiated, and the particular clinical end
23 point, and that it is not useful to confuse general
24 radiation protection concepts with the quantities
25 needed to score more therapeutic responses.

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1 MEMBER SULEIMAN: I didn't use effective
2 dose. I used dose equivalent.

3 MEMBER WILLIAMSON: Dose equivalent. I
4 would say don't use that either. We use, for example,
5 biologically equivalent dose, which can be defined in
6 maybe a very customized way for a given organ end
7 point. But I think the radiation protection
8 quantities aren't useful for these purposes.

9 CHAIRMAN MALMUD: Thank you. We have a
10 member of the public.

11 MS. WARBICK: Ann Warbick Cerone, MDS
12 Nordion.

13 I just want to point out that our company
14 does touch many of the products that are on your list
15 here. The Y90 microspheres, the Bexxar, we
16 manufacture that, we manufacture the Y90 chloride for
17 Zevalin, and we have touched in the past Samarium,
18 EDTMP. Just to let you know, too, that all these
19 isotopes are cross-calibrated directly with NIST, from
20 our perspective, and that many times customers will
21 ask for secondary standards, and we do provide those.

22 And also there's a move now for customers
23 to request an information or fact sheet that tells
24 them exactly what's contained in the product vial. So
25 that's an interesting move forward.

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1 CHAIRMAN MALMUD: Thank you.

2 Dr. Fisher.

3 MEMBER FISHER: I appreciate the talk that
4 you've given, Orhan, and we've discussed this a little
5 bit previously, and he makes a good point. But I
6 would differ with Dr. Eggli, that the problem is not
7 the MIRD equations. I serve on the MIRD committee and
8 have done so for more than a decade. It's perhaps in
9 the way the recommended system is applied. The
10 greatest source, really, of error is in determining
11 the actual activity present inside the body, in any
12 given organ, at any point in time, and that's probably
13 the major source of error in internal dose
14 calculations.

15 From a patient's right perspective, I
16 think it's important that we improve this area, the
17 state of the art. An analogy might be that, if I
18 compare it to the airline industry, we have in the
19 airline industry pilots who know how to fly the
20 airplane and they know where the destination is, but
21 in this particular case, they may not know how much
22 fuel they have on board or how much fuel is needed to
23 get to a particular destination.

24 And so dosimetry really is important for
25 knowing how much energy is imparted, and I would kind

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1 of agree with Orhan, that there is a lot of difference
2 in the way units are applied, just to answer the rim-
3 absorbed dose concept, question that came up. The
4 MIRDC committee is working on a better definition for
5 applying a quality factor with alpha particles, and I
6 think the concept that we're moving toward is the one
7 proposed by the NCRP for dealing with space radiation,
8 and that's to apply a gray equivalent dose in dealing
9 with absorbed dose from alpha particles.

10 CHAIRMAN MALMUD: Dr. Welsh.

11 MEMBER WELSH: I don't disagree that
12 there's a need for improved dosimetry and that there
13 is a role for understanding some of the things you've
14 brought up such as dose rate, which is flat out
15 ignored in many of these matters right now.

16 But the fact is that some of the studies
17 that have been done, understanding the limitations of
18 the models and the ability to estimate how much
19 activity is within a particular organ, have not
20 documented the correlation between tumor dose and
21 response, which was very surprising to me, that's the
22 way it came out, and true dosimetry estimates are
23 going to be very challenging, for the reasons we've
24 just discussed.

25 I think it would be perhaps a mistake to

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1 hold up or slow down, or not promote the use of
2 radiopharmaceuticals or radioimmunotherapy, in
3 particular because of a perceived concern that the
4 dosimetry is not state of the art right now.

5 The fact is that radioimmunotherapy and
6 radiopharmaceuticals, in general, are grossly
7 underutilized, and it has nothing to do, in my
8 opinion, with the issue of dosimetry. It has to do
9 with the gatekeeper mentality of those who manage
10 these patients.

11 And as you mention, some of these are last
12 resort therapies, when they should be first line or be
13 tested in first line, and the fact is that right now
14 it's not being done, not because of dosimetry.

15 I would ask if medical oncologists could
16 tell me how much adriamycin or cisplatin really got to
17 the tumor. With the limitations of the MIRD and what
18 we have right now, we can get a much better estimate
19 of how much radioimmunotherapy would get to the tumor,
20 yet it's not being utilized.

21 And my point might be that if anybody
22 needs to be educated or regulated, it might be our
23 medical oncology colleagues about the value of this
24 modality and that it needs to be thought of earlier
25 rather than later, because it is perhaps the most

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1 effective treatment there is for some of these
2 conditions.

3 CHAIRMAN MALMUD: Any other comments?

4 [No response]

5 CHAIRMAN MALMUD: Thank you, Dr. Suleiman.
6 I thank Dr. Welsh also for his insightful comments
7 with regard to the efficacy of this therapy versus
8 others that are currently in use.

9 MS. WASTLER: Dr. Malmud, I would suggest
10 that we are in a position where we could take our
11 break, which was originally scheduled at 2:45 and come
12 back for the final two presentations.

13 CHAIRMAN MALMUD: We will, and I just
14 would like to remind the group an that prior to taking
15 the break, would anyone leaving early please stop by
16 and talk to Ashley.

17 (A recess was taken from 2:41 p.m. to 3:00
18 p.m.)

19 (Whereupon, the foregoing matter went off
20 the record at 2:41 p.m. and went back on the record at
21 3:00 p.m.)

22 CHAIRMAN MALMUD: Ladies and gentlemen,
23 can we begin? Dr. Eggli is ready. Dr. Vetter sends
24 his regards.

25 MEMBER EGGLI: And his passion on this

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1 issue.

2 MS. WASTLER: Yes. I was informed that if
3 Dr. Eggli doesn't make this presentation there could
4 be dire consequences from Dr. Vetter.

5 CHAIRMAN MALMUD: All right.

6 (Off the record comments.)

7 CHAIRMAN MALMUD: Three of our members are
8 actually getting their photographic I.D. badges. So
9 we also celebrate that with them.

10 MS. WASTLER: A monumental occasion.

11 CHAIRMAN MALMUD: Yes, it means they can
12 get through the front door without a 20 minute delay.

13 (Off the record comments.)

14 MEMBER EGGLI: Dr. Malmud, should I go
15 ahead and start?

16 CHAIRMAN MALMUD: We are ready. If you
17 would begin, we would appreciate it very much.

18 MEMBER EGGLI: Thank you.

19 CHAIRMAN MALMUD: If you would like, I can
20 introduce you.

21 MEMBER EGGLI: Okay.

22 CHAIRMAN MALMUD: This is Dr. Eggli.

23 (Laughter.)

24 MEMBER EGGLI: I'm going to try to
25 represent some of Dr. Vetter's passion on this issue

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1 and the impact on the medical community. I was going
2 to put some graphic slide pictures in my presentation,
3 but I thought for the sensibilities of the audience I
4 would leave them out. But I will talk about the
5 graphic consequences of not being able to perform this
6 procedure as we go.

7 We have a number of objectives here this
8 afternoon to describe the current practice, to
9 demonstrate the safety of the practice, to identify
10 inconsistencies in guidance and to propose a
11 consistent application of Regulatory Guide 8.39,
12 Release of Patients Administered Radioactive
13 Materials.

14 Lymphoscintigraphy is a several step
15 process. Typically, less than a millicurie of sulfur
16 colloid either specially filtered or not is injected
17 into a patient to identify the lymph node drainage of
18 a tumor system. In step two, the patient is released
19 by the nuclear medicine department per Reg. Guide 8.39
20 and then step three, the patient has surgery to remove
21 either just the lymph nodes or sometimes the lymph
22 node and the primary tumor in the same setting.

23 This is sort of an image of what goes on
24 and I don't know if this will give me a -- there we
25 go. I have a pointer here. This is one of my

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1 favorite old gamma cameras and I don't know where Dick
2 got the picture of this but possibly at the
3 Smithsonian.

4 Yes, XRT-3000. We have radioactivity
5 injected either subcutaneously or subareolarly in the
6 breast shielded with a lead shield with the activity
7 subsequently draining to an axillary lymph node.
8 Although we inject in the order or the neighborhood of
9 approximately 1 millicurie or less, less than one
10 percent of that injected dose ends up in the lymph
11 node.

12 And here you can see we can often define
13 both the lymphovascular pathway and the lymph node
14 itself and the definition of a sentinel lymph node is
15 the first lymph node in any lymphovascular drainage
16 pathway. The significance of analyzing the sentinel
17 lymph node is that if it is tumor-free, that the lymph
18 nodes upstream are also tumor-free. The point of this
19 is to limit the magnitude of the lymph node dissection
20 that has to be performed to adequately stage the
21 patient's tumor. This is most commonly used in two
22 tumors currently in breast cancer and in malignant
23 melanoma.

24 So after imaging, a patient is released
25 and, in general, based on the Regulatory Guide 8.39,

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1 other medical procedures including surgery may be
2 performed, and there's additional guidance provided
3 under NRC Health Physics Position Statement No. 156
4 which is this whole long statement here which says "If
5 our licensee administers a radiopharmaceutical for a
6 licensed authorized procedure, it may conduct any
7 number of additional procedures whether they are
8 authorized or not provided that additional
9 administrations are not performed for the purposes of
10 the unauthorized procedure (although additional
11 authorized administrations may be needed for other
12 authorized procedures). The basis for the above is
13 that once a dose is administered to a patient for a
14 procedure that is authorized no additional harm from
15 radioactive materials can result to the patient during
16 the conduct of other medical procedures."

17 And if you look at other medical imaging
18 procedures that routinely are followed by other
19 medical procedures, myocardial perfusion imaging is
20 often followed by angiography, angioplasty or open
21 heart surgery. It is not uncommon that in the middle
22 of our procedure if we see a severe perfusion
23 abnormality that the patient goes directly to the
24 cardiac cath lab for intervention.

25 Thyroid scans are often followed by

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1 thyroidectomy. Tumor scans are followed by tumor
2 resection and lymphoscintigraphy is followed by
3 lymphadenectomy. This can be done in a variety of
4 settings. It can be hospital/same hospital,
5 hospital/different hospital, outpatient
6 clinic/hospital and mobile imaging center/hospital.
7 The bottom line is there is sort of a disconnect
8 between localization of the sentinel node and the
9 subsequent surgery that removes it.

10 And the people who are exposed are
11 typically the operating team and the pathologist, the
12 surgeons and the pathologist and if you look at some
13 data on the exposures and there's not a lot in the
14 literature and when you see these "less thans" these
15 less thans are the lower limits of the detection
16 systems in play, so that when we say less than 1.6 mR
17 or less than less than 2.2 mR that was the lower limit
18 of the detection system and so that a dose less than
19 that could be in the order of magnitude of Morton's
20 study where they were actually able to detect fairly
21 low levels and get 0.2 millirem or 0.25 millirem. So
22 that the radiation exposures to the other personnel
23 are really quite small.

24 The new NRC guidance from March, from the
25 quarterly newsletter in March of 2006, states that

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1 "Surgical removal of radioactive tissue and its biopsy
2 constitute the medical use of byproduct material in
3 imaging and localization studies and must be performed
4 at a licensed facility under the supervision of an
5 authorized user."

6 The consequences of the new guidance are
7 fairly significant particularly for rural medicine
8 outside of major metropolitan areas. Local nuclear
9 medicine service now can no longer provide
10 lymphoscintigraphy if the follow-up surgery is planned
11 at a hospital that is not licensed to handle the
12 radioactive material. And now you ask "So why would
13 anybody use a mobile nuclear medicine imaging
14 service?" It's probably because they are very small
15 volume and, in fact, the hospital doesn't have a
16 license. So these mobile imaging services are the
17 only access to these procedures that these patients
18 have.

19 And then we have the problem of money.
20 You know, "Money is the root of all evil" and
21 certainly the root of all insurance. A lot of
22 insurance requires that patients have their procedures
23 done in-network and if the in-network means a hospital
24 that does not have a license, the patient will then
25 have to be subjected to a radical lymphadenectomy

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1 which I'm going to talk about and which I did not
2 bring pictures of because of the sensibilities of the
3 audience seeing very swollen extremities with surgical
4 wounds that won't heal because the lymph can't drain
5 from the extremities.

6 There is significantly increased patient
7 morbidity if image guided sentinel node biopsy cannot
8 be performed and a formal axillary or inguinal lymph
9 node dissection has to be performed and let me explain
10 to you what a formal dissection is. That is the
11 effort to remove every single lymph node in that basin
12 and as a result, the lymphatic fluid does not drain
13 from that extremity. The wound may not heal. If it
14 heals, the patient has a problem with extremities
15 swelling for the rest of their lives. Every time they
16 have an injury to the extremity, they run the risk of
17 infection and they wear these both expensive and
18 uncomfortable garments that try to squeeze the
19 lymphatic fluid out of the extremity back into the
20 body without the benefit of a lymphatic drainage
21 pathway.

22 In addition, the cost of the operative
23 procedure, the operative risk and the recovery time
24 are far greater for a formal lymphadenectomy which
25 keeps the patient in the hospital two to three days as

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1 opposed to a sentinel node biopsy where the patient
2 leaves the hospital on a same day basis. And again,
3 the persistent lymphadema is a very difficult to
4 manage medical problem that is unnecessary to have to
5 manage and what it does is it subjects these patients
6 who do not have access to sentinel node localization
7 and image guided biopsy to a substandard care of
8 medical practice. So the regulation is now condemning
9 these patients to substandard care.

10 Hospitals not licensed to handle
11 radioactive materials then would either have to
12 purchase a license and then contract for services with
13 an authorized user, an RSO, which again unnecessarily
14 increases the cost of delivery of health care. This
15 guidance is inconsistent with Regulatory Guide 8.39
16 which allows the release of patients that contain less
17 than 150 millicuries of technetium and directly
18 contradicts the Health Physics Position Statement No.
19 156.

20 So the recommendation is that to
21 facilitate best practices of medicine and put the
22 needs of the patient first, lymphoscintigraphy should
23 be allowed. The patient should be released
24 unconditionally. The surgery of these released
25 patients at hospitals that do not contain materials

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1 licenses should be allowed.

2 However, it is reasonable to require
3 hospital, clinics or mobile services to education
4 applicable surgical and pathological personnel at the
5 unlicensed hospital. I don't know if the article was
6 distributed, but there were recommendations for
7 handling radioactive specimens obtained by sentinel
8 lymphadenectomy published by the Surgical Pathology
9 Committee of the American College of Pathologists and
10 the Association of Anatomic and Surgical Pathology
11 Directors in the year 2000, and I have a copy of that
12 article with me. I can provide the reference if we
13 didn't distribute that. And then I promised I would
14 take less than 15 minutes. Have I done that, Sandi?

15 MS. WASTLER: Yes, you have.

16 MEMBER EGGLI: Hot dog.

17 MS. WASTLER: Fourteen minutes.

18 MEMBER EGGLI: Any questions from the
19 audience for me?

20 MS. WASTLER: Boy, talk about a person on
21 a mission. Very good.

22 I would ask though that one thing that we
23 were going to do. Donna-Beth is going to talk about
24 the basis for our position, and so it might be good or
25 I would suggest that it might be good for Donna-Beth

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1 to give her presentation and then open up the entire
2 discussion.

3 CHAIRMAN MALMUD: Sounds good.

4 (Off the record comments.)

5 MS. WASTLER: They have the slides. Why
6 don't we go ahead just rather than to hold up because
7 of the technical difficulty. Let's talk from the
8 handouts and then we'll see about getting the
9 technical difficulty fixed.

10 DR. HOWE: Okay. We had a technical
11 assistance request from one of our regions. We had a
12 licensee that requested the surgical part of sentinel
13 lymph node biopsy to be done at one of their hospitals
14 that was not licensed. We evaluated the request, and
15 essentially we're in agreement with Dr. Eggli's
16 presentation that technetium is used with the
17 localization and surgical removal of radioactive
18 tissue, but our position is that the technetium that
19 is used for the localization and surgical removal of
20 tissue is not exempt from the requirements for a
21 license, that it is regulated right now under 10 CFR
22 35.200 and that the surgeon using the radioactive
23 materials in the patients to localize the radioactive
24 sentinel nodes. So we considered the surgical removal
25 to be completion of the procedure of the original

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1 image -- of the imaging and localization procedure.

2 And the material, that it's a medical use
3 for the byproduct material and it needs to be
4 performed in a licensed medical use facility under the
5 supervision of an authorized user and in an operating
6 radiation safety program under the supervision of
7 radiation safety officer. What we have done in a
8 number of cases in various regions is that we have
9 licensed the surgical suite area which may be in a
10 different facility as a satellite facility to a larger
11 licensee that provides the nuclear medicine.

12 MS. WASTLER: Go ahead, Donna-Beth.

13 DR. HOWE: Okay. The third slide
14 essentially shows that there is the injection of the
15 radioactive material. There are several components
16 versus the injection of the radioactive material. The
17 second is the biopsy and surgical removal of the
18 radioactive lymph node. The third is the pathology
19 laboratory and the fourth would be the disposal of the
20 radioactive material.

21 If you look at the injection part, the
22 injection is performed under the supervision of an
23 authorized user. The authorized user in this case,
24 this is -- I have a 920 on there because I picked it
25 up and didn't edit it quite right. The authorized

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1 user meets the training and experience requirements of
2 35.290 because it is imaging and localization.

3 We believe the surgical part of the biopsy
4 is the medical use of byproduct material. Currently,
5 we consider that to be completion of the procedure.
6 It would be covered by 35.200, Imaging and
7 Localization. I'll talk to you later about another
8 possibility.

9 The biopsy materials are radioactive
10 material whether they are licensed radioactive -- and
11 this is assuming that the material goes to a pathology
12 department that is not licensed. If the material
13 contains 100 microcuries or less of technetium-99m it
14 can go to an unlicensed pathology lab and it can
15 travel under an exempt quantities provision in 10 CFR
16 30.18. And the pathology lab is exempt from
17 licensing. If the tissue, however, contains -- so
18 there is a need to assure that the material in the
19 tissue contains less than 100 microcuries of
20 technetium.

21 If the tissue contains over 100
22 microcuries of technetium-99m, then it can only be
23 transferred to another licensee. In this case, the
24 pathology laboratory needs to be licensed and the
25 licensee needs to ship the radioactive material in

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1 accordance with DOT requirements and verify that the
2 recipient is authorized to receive the material. The
3 remaining material in lymphoscintigraphy needs to be
4 disposed of radioactive waste. We think the preferred
5 method of disposal is decay in storage so that once it
6 is held, it can be thrown away as regular waste.

7 Okay. When we answered the TAR, we were
8 asked, "Can we do this in an unlicensed facility?" We
9 said, "No." We offered them a mechanism that we have
10 used before to license the facility as a satellite.
11 The next question is "Can the surgeon become an
12 authorized user" and, "If so, would the surgeon need
13 to meet the requirements of 35.290?" If we break the
14 imaging and localization procedure into its two
15 component parts, it's very clear that the injection
16 part of the procedure would come under the nuclear
17 medicine physician that meets the requirements in 290.
18 When you look at the surgical requirements, it's
19 pretty easy to see that the surgical requirements from
20 a radiation safety point of view are not as extensive
21 as the overall training and education mode a 200
22 physician would need.

23 So we could handle a surgeon becoming an
24 authorized user under 35.1000. We would probably put
25 it under 35.1000 because our position would be that he

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1 did not require the full 700 hours of training and
2 experience and all the imaging and localization for
3 the 290 but would require some lesser amount of
4 training and in tasks that were specific to his use of
5 the material, his identification of the tissue as
6 either being radioactive or exempt from licensing to
7 go to a pathology lab.

8 And so far, we haven't received another
9 request for that, but I think that's the position that
10 we would take is that we can license the surgical
11 suite independently under 35.1000.

12 CHAIRMAN MALMUD: Thank you, Dr. Howe.
13 Dr. Nag.

14 MEMBER NAG: I am wondering if the two
15 components can be separated because if the injection
16 was done, for example, in a mobile facility or in a
17 different hospital and the surgical portion of the
18 removal was done in a different hospital, that can be
19 handled in a separate manner from one where the
20 injection and the surgical are done in the same place
21 because the risk of doing the injection and so forth.
22 So that component I think has to be under some type of
23 licensing, you know, 219 and so forth.

24 However, I think to extend and say because
25 that tissue is radioactive and it is in a different

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1 hospital because it is radioactive, although very low
2 amount, now you want to apply all the rules for
3 radioactivity, I think, is extending far beyond NRC
4 law. For example, we do radiation implants, permanent
5 implants. Those patients once in a while, some of
6 them may die and then you have to do an autopsy and
7 they are not subjected although the amount of
8 radiation is far higher.

9 So I think you are extending the role of
10 NRC beyond what is required, at least in my opinion.
11 I would like to separate the two, the injection and
12 the surgical part. So if the injection is done in a
13 center that has all the licensing information to do
14 the injection, that could be done and then the surgery
15 could be done in a place that doesn't have a license.

16 DR. HOWE: Dr. Nag, that's almost the
17 proposal we have and that is we would consider
18 licensing the surgical area separately from the
19 injection, but it is still license material and needs
20 to come under license. There is an assumption and the
21 licensee made the same assumption that 10 CFR 35.75
22 sets a limit in which NRC considers the medical use to
23 be a licensed activity. But, in fact, you're still
24 using this licensed material for its one intent,
25 imaging and localization, and you have not completed

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1 the procedure. It's not that different from many of
2 our other procedures where you have bone scans where
3 you release patients because you don't have to
4 hospitalize them. But you expect them to come back to
5 the licensee for the completion of the procedure. In
6 this case, you're working on completion of the
7 procedure.

8 We also looked very carefully at 35.75 and
9 determined that the assumptions that you're basing
10 your release in 35.75 are that the patient will resume
11 normal activities and with some restriction on close
12 contact to others and that the radioactive material
13 and the radiation sources contained within the subject
14 are released primarily to the sanitary sewer through
15 normal biological processes. We did a careful look at
16 our regulation and our indications for use and there
17 is no indication that the regulation or the regulatory
18 history in 35.75 was intended to encompass surgical
19 excision of radioactive material that was implanted
20 for that particular surgical excision and so it is a
21 completion of the procedure and 35.75 is not the
22 applicable part of the regulation.

23 MEMBER NAG: I think that is why we keep
24 on saying that there should be some judgment exercise
25 about how much do you want to stretch a rule versus

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1 what the relative medical importance, what is the
2 radiological risk. Because if the risk is that
3 therefore that patient will now undergo a radical
4 surgery of the node, I think that's far worse than
5 whatever risk you may place by having 100 millicuries
6 of radioactive material.

7 MEMBER EGGLI: Microcurie.

8 MEMBER NAG: Microcurie. I'm sorry.

9 CHAIRMAN MALMUD: Dr. Eggli.

10 MEMBER EGGLI: I have to disagree with
11 staff's position on the procedure is not complete.
12 The procedure is complete when the patient leaves my
13 department. I have taken images. I have made a mark
14 on the skin which localizes the node and from that
15 point of view, this procedure is complete. The
16 Standard Medical Terminology Committee defines these
17 as separate and distinct medical procedures. So NRC
18 is changing that definition as well.

19 And then what we're talking about is for
20 a couple of microcuries of radioactivity, you are
21 going to subject patients to a very morbid procedure
22 or deny them health care which is now the standard of
23 care over a couple of microcuries of technetium, and
24 I think that's a very difficult position to support,
25 and I would like to see if our patient advocate would

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1 have a comment on that.

2 DR. HOWE: We are not denying the --

3 MEMBER EGGLI: Yes, you are because if the
4 insurance company requires the procedure done in-
5 network to pay for it and the hospital is unlicensed,
6 you are de facto denying the patient standard of care.
7 There is no other way to interpret that.

8 CHAIRMAN MALMUD: If we may get to the
9 heart of the matter. Why can't the two procedures be
10 considered separate procedures? It's unclear to me
11 why they are not separate procedures. When we do
12 thyroid imaging or parathyroid imaging with specific
13 radiopharmaceuticals, it's with the intention of
14 removing the tumor when it's found or the organ and
15 the patient may have more than a few microcuries of
16 the isotope on board at the time of the surgery.
17 These are two separate procedures done by two separate
18 departments and often not even done in the same
19 hospital.

20 Why is it that we see the lymph node in
21 the breast as part of a procedure when the parathyroid
22 in the neck which is imaged with technetium sestamibi
23 is not seen as part of the procedure? Isn't there a
24 precedent already? What I'm trying to do is see if
25 there's a precedent within the NRC practices which

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1 would encompass this and the two that I can think of
2 readily are thyroid imaging and parathyroid imaging
3 when the adenoma takes up the technetium-99m sestamibi
4 and is removed surgically.

5 DR. HOWE: It's also our understanding
6 that you use the radioactivity that's in the lymph
7 node to identify the sentinel lymph node with probes
8 and you're measuring the location to ensure that the
9 surgeon is removing the right lymph node with the
10 radioactivity.

11 CHAIRMAN MALMUD: So do we with the
12 parathyroid.

13 DR. HOWE: And you're using radiation.

14 CHAIRMAN MALMUD: We actually would do
15 that with the parathyroid also. The surgeon is given
16 a probe to identify it intra-operatively. So it's not
17 unique. I'm trying to help us, all of us.

18 MEMBER EGGLI: It's the fortuitous
19 consequence of an imaging procedure.

20 CHAIRMAN MALMUD: There may be a precedent
21 that exists clinically that the NRC could see as an
22 example of how this particular study could be
23 encompassed in the same kind of thinking and I think
24 parathyroids in particular are a better analogy even
25 than thyroid because in the case of thyroid, the tumor

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1 itself, the initial tumor, is cold, whereas with
2 parathyroid the adenoma is lighting up.

3 So the precedent does exist if we can
4 somehow say we are already doing something like this
5 and this is another example of it. It is true that
6 the woman would be subjected to a more radical
7 surgical procedure and a worse outcome without this
8 procedure than with it. So in a sense, we are part of
9 a system that would be denying the advantage of that
10 care and it's also true that the insurance companies
11 now direct the patients to specific institutions, some
12 of which may not be licensed to do the nuclear
13 medicine procedure preoperatively. But the removal of
14 a couple of microcuries of technetium-99m is really a
15 very minimal thing and one for which there is a
16 precedent.

17 DR. HOWE: Now when you do your
18 parathyroid removal, do you send your patients to
19 another facility?

20 CHAIRMAN MALMUD: No, we're at a
21 university hospital. We do the whole thing
22 internally.

23 MEMBER EGGLI: But the answer to that --
24 is the answer to that could be yes?

25 CHAIRMAN MALMUD: The answer --

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1 DR. HOWE: How often is it yes?

2 MEMBER EGGLI: I'm not here to talk about
3 that today, but the answer could be yes.

4 CHAIRMAN MALMUD: There is no reason why
5 it couldn't be, why the answer couldn't be yes and it
6 may be that the patient's surgeon is at an institution
7 that doesn't have the nuclear medicine facility
8 available to do this and therefore it's done elsewhere
9 and then the surgery is done in the smaller
10 institution.

11 I'm sure there must be somewhere examples
12 of this that might be useful in figuring out how we
13 overcome what appears to be a regulatory impasse.

14 DR. HOWE: And then when they pull the
15 radioactive parathyroid tissue out, do they send it
16 off to pathology or --

17 CHAIRMAN MALMUD: It goes to pathology.

18 DR. HOWE: -- or does the fact that it is
19 already radioactive is enough that --

20 CHAIRMAN MALMUD: The amount of
21 radioactivity is quite trivial. I mean we handle more
22 radioactivity than that on a daily basis in patients
23 who undergo technetium-99m imaging for bone scans and
24 so on and at the same time, they may have a blood
25 specimen drawn that day and they have technetium-99m

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1 in that blood tube that's being sent off to the lab to
2 be processed for chemistry. There is technetium
3 floating around the place all day long.

4 DR. HOWE: I understand that.

5 CHAIRMAN MALMUD: Not to mention urinary
6 excretion of radioisotopes which are a sore subject
7 for all of us in terms of the patients who may be
8 incontinent or catheters that are leaking. Dr.
9 Fisher.

10 MEMBER FISHER: Thank you. It has been my
11 perspective that in most cases the Nuclear Regulatory
12 Commission tries to come up with rulemaking and
13 decisions that are in the best interest of society and
14 the best interest of not only radiation protection but
15 also in the best interest of the patient in terms of
16 clinical benefit. Otherwise, you would be outlawing
17 all radionuclide procedures and all uses of radiation.
18 Clearly, there's a medical benefit.

19 My concern here is that the NRC may be
20 looking at the regulations a little bit too closely in
21 terms of the letter of the law while ignoring the
22 benefit to the patient in use of what really is a very
23 trivial amount of a very safe radionuclide. Among all
24 radionuclides used in medicine, I can't think of one
25 that is perhaps more safe and effective than

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1 technetium-99m in terms of what is the risk of a
2 misadministration or a risk of a spill. It's really
3 a very good choice.

4 And I would urge the Nuclear Regulatory
5 Commission to very seriously consider the proposal
6 from Dr. Eggli and the rest of this advisory committee
7 that there are cases where patient benefit may be more
8 important than letter of current law, and the NRC has
9 the ability to change its regulations to take these
10 important factors into account so that the benefits of
11 a treatment outweigh other considerations. So I would
12 very much support this.

13 CHAIRMAN MALMUD: Thank you. Ms. Schwarz.

14 MEMBER SCHWARZ: And I wanted just to add
15 the fact of being a woman on this committee and I
16 think that I'm speaking for women. This is certainly
17 something that should be considered. It's a very
18 benign procedure and the people who would benefit
19 typically would be a very small community or an
20 insurance issue and maybe possibly poorer people that
21 couldn't afford to go to a different institution that
22 could accommodate the type of procedure. So again, we
23 have to think that it's a limited number of people
24 that will be in this position but certainly would be
25 tremendously benefitted by the availability of being

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1 able without regulatory constraint to actually obtain
2 this procedure.

3 CHAIRMAN MALMUD: Thank you. Dr. --

4 MEMBER WILLIAMSON: Yes, I would just say
5 that my own immediate family has been a beneficiary of
6 the fact that this procedure has not been policed in
7 this intrusive way as you propose, that in case in
8 point the patient had the outpatient administration --
9 nuclear medicine imaging done in one outpatient
10 facility and had the surgery done in a different
11 outpatient facility and would not have been able to
12 have the choice of surgeon had this rule been imposed
13 in this way.

14 So I think I, too, would urge the staff
15 to consider the merits of Dr. Eggli's procedure.
16 Perhaps if you can't make it fit the letter of the law
17 what you should do is put it in 35.1000 so that you
18 specifically can relieve the surgeon from the burden
19 of having to become a licensed personage and the
20 surgical facility from having to become a licensee or
21 satellite licensee.

22 CHAIRMAN MALMUD: Mr. Lieto.

23 MEMBER LIETO: I am kind of opposed to
24 adding things to 1000. It just seems like we're
25 setting up a bureaucracy that's really totally

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1 unnecessary.

2 It seems like one driving philosophy that
3 is being missed here is ALARA. This is totally --
4 what's being recommended here is not reasonable and
5 there's not any health or safety issue that this whole
6 additional mechanism that's being proposed here is
7 addressing. What we're doing is we're setting up a
8 whole set of rules and requirements on surgeons
9 because he takes a node out and puts it in a tube and
10 hands it to a pathology tech just so that this
11 procedure can be done.

12 At our health system, we're actually kind
13 of affected by this directly. The issue that goes on
14 is not so much the surgeons. It's that in larger
15 systems pathology services are centralized for
16 economic reasons and so forth. So where the node is
17 removed has to be sent, maybe sent, via -- is taken
18 out in a hospital that's not licensed and sent to
19 another pathology area where it's analyzed. We had to
20 set up a whole mechanism for transport just simply
21 because the fact that we are putting radioactive
22 materials on public roads.

23 But the point is that there's not any
24 health or safety -- especially in an OR environment.
25 The biohazard environment of that surgical procedure

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1 so far exceeds the radiological it's not funny and so
2 what we're doing is we're creating a whole set of
3 requirements where again I think keeping things as low
4 as reasonably achievable is kind of being lost in this
5 procedure.

6 And the other thing that I wanted to point
7 out was a follow-up to Sally's statement. This is
8 going to increase. Sentinel node procedures are now
9 or have within the past year or two become the
10 standard of care in the management of patients with
11 breast cancer. So this is going to become a greater
12 procedure or a procedure of greater need in rural
13 areas than it is even now and I think setting up
14 something like this just -- you are going to prevent
15 patients because surgeons will not go through this
16 process. Okay. They're just not going to become
17 authorized users or ask to be named on a license
18 because they're doing surgery in Hospital X and
19 Hospital Y and so forth and you're going to set up a
20 whole system of license amendments just because of a
21 couple of microcuries of technetium, and it just
22 doesn't seem reasonable.

23 CHAIRMAN MALMUD: Dr. Nag.

24 MEMBER NAG: Yes.

25 DR. HOWE: I think there's one thing the

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1 ACMUI needs to recognize, and that is that NRC doesn't
2 have a lower threshold of radioactivity which you can
3 use byproduct material that doesn't require a license
4 unless it comes under a very narrow set of regulations
5 and 30.14 through 30.21 and this is not in that
6 category right now. We don't have -- at one point, we
7 had something that the NRC had proposed. It was
8 called below regulatory concern and that went out on
9 a Friday and died on a Monday.

10 CHAIRMAN MALMUD: Dr. Nag.

11 MEMBER NAG: I have been very much
12 impressed with the Commissioners that whenever the
13 ACMUI has met directly with the Commissioners, the
14 Commissioners always say that the overriding factor
15 should be the access to care, the availability of good
16 care for the patients and therefore, if something is
17 said just purely because of a regulatory issue but not
18 a safety issue, those should be overridden for the
19 overall benefit. So I would definitely bring this up
20 directly with the Commissioners.

21 MS. WASTLER: I don't think we even need
22 to go to that level.

23 CHAIRMAN MALMUD: If I may --

24 MS. WASTLER: What we're here for is to
25 raise an issue. When we did this, I mean, it wasn't

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1 with the intended consequence of keeping patients from
2 getting treated. I mean, this was an unintended
3 consequence, and we're here to discuss it, and we will
4 go back and relook at the situation because that's not
5 what we intended.

6 CHAIRMAN MALMUD: Yes, and I fully agree
7 with your statement and that's why I made the point
8 that I did earlier. It's been my experience that when
9 these kinds of issues arise that staff, that NRC
10 staff, tries to reinterpret within the law the
11 regulations to allow for this kind of humane practice
12 to exist in various situations and there has been
13 flexibility and that's why I think that if you and the
14 staff look, you'll see that there is precedent and
15 there are many examples we can cite of organs that are
16 imaged and then promptly removed which have far more
17 radioactivity in them and are then processed. Besides
18 blood, there are other organs that we look at.
19 There's a kidney scanning for tumor and then a
20 nephrectomy is performed promptly while the kidney
21 still has some residual activity in it I'm sure and
22 urine and blood.

23 MEMBER NAG: Liver scans.

24 CHAIRMAN MALMUD: Liver scans, generally
25 the liver remains in, but there are some situations in

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1 which it may not.

2 Biopsies, malignant bone lesions which are
3 promptly operated on. Fractures which are operated
4 on. They are picked up because the other imaging
5 techniques don't detect them and the nuclear medicine
6 technique does. Then they go to surgery. They're
7 still slightly radioactive. There isn't that much
8 activity there. So I think that there is precedent in
9 the practices over the past decades that would allow
10 some flexibility if your staff is given time to look
11 for them.

12 MS. WASTLER: And I think -- I would just
13 say for my benefit I don't recall -- I mean, the
14 consequences that Dr. Eggli brought up with regards to
15 the mobile nuclear option and the insurance
16 restriction option were not issues that we were aware
17 of. At least, I personally wasn't aware of and I
18 don't think my staff was. So these are additional
19 pieces of information that I think we need to consider
20 and see what we can do with regards to --

21 MEMBER WILLIAMSON: Also choice of
22 practitioner and facility. There are patients' wishes
23 to be honored here and I think there is no safety
24 issue at stake.

25 CHAIRMAN MALMUD: Dr. Suleiman.

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1 MEMBER SULEIMAN: How does this fit into
2 the risk-based paradigm because clearly we're not
3 dealing with a high level of risk here? So how did
4 this get into the --

5 DR. HOWE: We regulate many things with
6 very, very low risk. Our level of when we regulate
7 does not come into play with risk but the amount of
8 regulation that we apply to things we try to apply in
9 a risk-based manner.

10 We do have persons that are exempt from
11 licensing. We have very specific uses of material and
12 types of material that can be used by persons exempt
13 from licensing. Those are our lowest risks and we go
14 through extensive review of that for setting that up
15 and then we have general licenses which don't require
16 much more regulation. Then we have specific licenses.
17 But if you also look at Part 35, you'll see that we do
18 have regulations in place for 35.100 uses which are
19 very low risk.

20 MEMBER SULEIMAN: My concern in this case
21 would -- how much radiation could the surgeon
22 received.

23 DR. HOWE: The estimates we have, it's
24 pretty low, but we don't have a regulation that says
25 if you get below a 100 millirem in a year then you're

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1 not regulated. We --

2 MS. WASTLER: You did some calculations.

3 DR. HOWE: We did some calculations.

4 MEMBER. SULEIMAN: Clearly, that's an
5 indicator of risk, obviously, if you've been picking
6 up very little quantities.

7 DR. HOWE: We have policy that was below
8 regulatory concern and this was a number of years ago
9 and that was risk-based and that did not last more
10 than a few days.

11 CHAIRMAN MALMUD: I think Dr. Zelac was
12 next and then we'll --

13 DR. ZELAC: I think we're moving in a
14 direction for the entire issue, but there is one
15 aspect of it that I would like to bring up for
16 possible further consideration and that's the mention
17 that Dr. Eggli made of specific coding require
18 hospital, clinic or mobile license to perform
19 lymphoscintigraphy to educate applicable surgical and
20 pathological personnel at unlicensed hospital, etc.
21 Now I think for us that becomes an issue to try to
22 accomplish the objective of having people in these
23 facilities, handling these materials, that have an
24 awareness of what it is that they're doing. Because
25 I know that at least in some facilities, there is

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1 apprehension and concern because it's radioactive. It
2 doesn't matter the amount. It's radioactive. I'm
3 concerned working in the facility, handling these
4 specimens. These people need to be educated, but I'm
5 not sure that this suggestion is the way that it can
6 be accomplished.

7 CHAIRMAN MALMUD: Dr. Welsh and then Dr.
8 Nag.

9 MEMBER WELSH: I have a quick comment from
10 the perspective of the clinician who practices in the
11 rural areas and the practice, the standard of care,
12 two years ago was not inclusive of sentinel lymph node
13 biopsy because the surgeons were not trained in that.
14 So when a patient who presented with a breast tumor
15 and had a lumpectomy was now given the option of
16 axillary lymph node dissection which we heard from Dr.
17 Eggli carries significant morbidity versus radiation
18 therapy to the axilla empirically because that patient
19 might have a 20 percent risk of having a node
20 involved, it must be kept in mind that axillary
21 radiation carries significant morbidity, too. So the
22 patient was initially told from the surgeon "I don't
23 know how to do a sentinel lymph node biopsy. So you
24 won't have that, but you won't have an axillary lymph
25 node dissection because that's a very morbid procedure

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1 and your risk of having a node that's involved is
2 small."

3 But when I met with the patient and
4 calculated the risk, it might be about 20 percent and
5 the patient elected to go ahead with axillary lymph
6 node radiation. This could simply have been avoided
7 by a sentinel lymph node biopsy and it needs to be
8 kept in mind that the alternative to axillary
9 dissection which is radiation therapy to the axilla
10 carries significant morbidity itself, potential
11 morbidity, and sentinel lymph node biopsy is a
12 medically simple way of avoiding both of those morbid
13 procedures in appropriate clinical context.

14 CHAIRMAN MALMUD: Dr. Eggli.

15 MEMBER EGGLI: And again if you go back to
16 the slide that references the little bit of data on
17 exposure to surgeons and pathologists, virtually with
18 the exception of Morton who measured very low, they
19 are all off the bottom end of the detection system.
20 So the radiation exposure the individual surgeon
21 received or the individual pathologist received is
22 somewhere off the bottom end of our ability to measure
23 it. These are again very, very low exposures.

24 I understand what Dr. Howe says that in
25 regulatory space there is no lower limit. But again,

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1 if you look at risk versus benefit, there is virtually
2 no risk and the benefit is staggeringly high.

3 CHAIRMAN MALMUD: Dr. Nag.

4 MEMBER NAG: Yes. May I offer a motion?

5 CHAIRMAN MALMUD: Certainly.

6 MEMBER NAG: I'll make a motion that for
7 sentinel lymph node biopsies the injection of the
8 radioactive material be done under the supervision or
9 under someone with certified 290. However, the
10 subsequent surgical procedure does not need to be
11 performed under any other licensing procedure. I mean
12 the wording can be manipulated, but the idea is that
13 the injection has to be under 290 but then not the
14 removal. Up to after the injection and the imaging
15 has been done, that's considered the end of the
16 procedure.

17 CHAIRMAN MALMUD: That's a motion.

18 MEMBER NAG: Yes.

19 CHAIRMAN MALMUD: Is there a second to the
20 motion?

21 MEMBER NAG: I mean you can modify the
22 second -- reword as needed, but that's the --

23 CHAIRMAN MALMUD: The motion is that the
24 injection for a sentinel lymph node biopsy is a
25 procedure unto itself. The surgical removal of that

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1 node later on is a separate procedure which is not a
2 part of the nuclear medicine procedure and should not
3 be regulated. That's your suggestion.

4 MEMBER NAG: Yes.

5 CHAIRMAN MALMUD: And do you want to add
6 a correlate if there are existing precedence for this
7 in other organs and other tissues?

8 MEMBER NAG: Yes.

9 CHAIRMAN MALMUD: That is the motion. Is
10 that acceptable?

11 MEMBER EGGLI: I second it. I was the
12 second. I accept that.

13 CHAIRMAN MALMUD: Any discussion of that
14 motion?

15 (No response.)

16 CHAIRMAN MALMUD: All in favor?

17 (Show of hands.)

18 CHAIRMAN MALMUD: Any opposed?

19 (No response.)

20 CHAIRMAN MALMUD: So it's unanimous.

21 DR. HOWE: Thank you very much.

22 CHAIRMAN MALMUD: So that's a
23 recommendation to decouple the two. The surgical
24 removal is no more significant than the surgical
25 removal of any other tissue specimen in a body that

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1 has had any kind of diagnostic imaging, nuclear
2 medicine procedure done within a day in advance.

3 MS. WASTLER: Thank you.

4 CHAIRMAN MALMUD: And therefore, there's
5 precedent for it. I'm trying to help you out with the
6 precedents since I know that's the basis on which you
7 --

8 MS. WASTLER: As we look into this more,
9 we may be contacting you to try to get some additional
10 information on similar precedent.

11 CHAIRMAN MALMUD: Sure. Okay. Great.
12 Thank you very much. The next item on the agenda is?

13 MR. METZGER: So far 100 percent of them
14 are able to do it.

15 MS. WASTLER: Dr. Nag.

16 (Off the record comments.)

17 MEMBER NAG: I have the slides submitted
18 in hard copy; you may want them. Basically disclosure
19 that I have obtained slides and information about some
20 of these new emerging technologies from Isoray, Xoft
21 and Neovista, but I do not have any financial interest
22 in them.

23 The things we'll talk about are cesium-
24 131, the electronic brachytherapy and a strontium eye
25 applicator. Now for low energy nuclides like a

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1 cesium-131 it's not new. The idea of having low
2 energy soft x-ray, short half-life isotopes have been
3 there even before I started with my residency because
4 they have a limited depth of penetration, minimal
5 damage, ease of shielding, and at that time in 1958,
6 three isotopes were talked about. One was iodine-125,
7 palladium-103, and cesium-131.

8 Although from a radiobiological view point
9 cesium-131 as I'll show you later is probably the
10 better one, the one that was marketed first was I-125
11 because it was easy or had a lower cost and easy to
12 manufacture. This was done by Donald Lawrence and
13 then a few years later, Theragenics produced the
14 palladium-103 seed that was actually approved in 1987.

15 What are some of the problems with these
16 seeds? I-125 had a relatively long half-life of 60
17 days. So what's the big deal? Two problems. One is
18 that if you have a long half-life in a permanent
19 implant, the initial dose rate is low. If the initial
20 dose rate is low and you have a fast or rapidly
21 proliferating tumor, you may be ineffective. So I-125
22 would be effective in a slow-growing tumor like most
23 prostate cancer. However, if you have a rapidly
24 growing tumor, it may be ineffective and because the
25 half-life is 60 days, you have to have radiation

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1 protection to some extent for ten half-lives.

2 But palladium-103 has a much faster or
3 much shorter half-life, therefore, has a higher dose
4 rate so it's more effective theoretically. However,
5 the energy is much lower, 21KeV, which means that if
6 the seeds are very far apart, more than 1.5 cm apart,
7 you have may have cold spots in between.

8 A chemist at the Pacific Northwest
9 National Lab, Lane Bray, had the process of
10 economically separating and purifying cesium-131 in
11 1998 and therefore founded with Don Lawrence the
12 IsoRay Medical and the seeds were approved in 2003.
13 From the outside, the cesium -- I'm sorry, cesium-137,
14 the cesium-131 not 137, the cesium-131 is identical
15 with iodine. So from the outside, it's the same. The
16 same equipment can be used and so forth.

17 So what are the -- where are they used?
18 Like other iodine, it's used mainly for permanent
19 prostate implants. We've had about 500,000 cases
20 worldwide. You can use it for permanent implant at
21 other sites, for example, breast. Apparently very few
22 people are using permanent implant in the breast, but
23 you could. You could also use it as a removable
24 implant for eye plaques or even in breast implants.

25 But what are the differences between these

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1 three? Well, cesium-131 has the shortest half-life,
2 nine days, as opposed to 17 or 60 days. Therefore, it
3 has the higher initial dose rate and most of the dose
4 or 90 percent is delivered within one month as opposed
5 to two months or ten months for pallidum and iodine.

6 The other thing is biological
7 effectiveness. For most tumors, you need a half-life
8 for a permanent implant, a half-life of four to 17
9 days for the optimum half-life. If a tumor is fast
10 repopulating or highly proliferating, you need
11 something with an even shorter half-life. So from a
12 theoretical standpoint, cesium-131 would probably be
13 most efficacious of the three for the fast
14 repopulation tumor.

15 And because of the short half-life, most
16 of the radiation is delivered in one month. So you
17 don't have to worry about radiation safety after that
18 period. There are a couple of other things because of
19 the short half-life. The tumor, there are two things
20 you have to think about. (1) If you are implanting in
21 a tumor as opposed to prostate which is a normal
22 organ, if you are implanting an organ that is
23 principally made of tumor, the tumor may regress very,
24 very quickly which means the seeds can come closer
25 together very rapidly and that may even deliver a

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1 higher dose than what you're projecting.

2 In the prostate, it may be the reverse
3 because in the prostate when you implant, there are
4 very few tumor cells, it's mainly a normal organ and
5 initially prostate expands because of edema and then
6 slowly comes down and if you are giving the radiation
7 very fast, you may be giving most of the radiation
8 before the prostate has a chance to resolve the edema.
9 These are things you have to keep in mind.

10 The other thing you have to keep in mind
11 is because the half-life is so short, you have to use
12 it within two or three days of delivery as opposed to
13 iodine where if you cancel the case, you can
14 reschedule it for next week. A slight difference. Of
15 the three the cesium-131 is having very little
16 anisotropy. Anisotropy means if you can see the
17 dipping in, there's relatively little dipping in on
18 cesium-131 seeds when compared to palladium or iodine.
19 So technically or theoretically, it's much better.
20 However, from a practical viewpoint or pharmaceutical
21 viewpoint, it really may not make much difference
22 because there are so many seeds that the anisotropy
23 cancels each other.

24 Now the energy, the energy of cesium is
25 higher than that of palladium and very similar to that

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1 of iodine and therefore the inter-seed spacing may not
2 matter too much. So even if you are more than 1.5 cm
3 apart, you may not have a cold spot.

4 Now history of what the current state is.
5 As of October 2004, that's about three years ago, the
6 first patient was treated with cesium-131. About 1200
7 patients have been treated so far in about 45 centers
8 and perhaps another 25 centers are about to use I-125.
9 So we may have about 60 centers by the end of the
10 year.

11 What are the concentrations from a
12 radiation safety and regulatory standpoint? Size-wise
13 it's similar to I-125 or palladium, similar in energy
14 to iodine. The only difference is that you need a
15 shorter time for storage until decay and therefore
16 there may not be major differences in terms of the
17 regulatory standpoint.

18 The clinical future, I think,
19 radiobiologically it's a better isotope than iodine or
20 palladium from a radiobiology standpoint, however, we
21 don't know if this radiobiological advantage would
22 translate to better clinical outcomes. This remains
23 to be seen in a few years. Practically, the shorter
24 half-life may present a problem if a case is
25 postponed. However, you have to remember that

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1 nowadays we order the seed per patient. So it's not
2 that we order a lot of seeds and keep them on-hand.
3 So it may or may not present too much of a problem.

4 I think -- should I go onto all the
5 treatments and cases and then have questions?

6 CHAIRMAN MALMUD: Yes.

7 MEMBER NAG: Okay. The next one is the
8 new technology called Xofter Axxent Electronic
9 Brachytherapy System. Now what is brachytherapy? We
10 are coming to the heart of a definition.
11 Brachytherapy, the strict definition, is the treatment
12 of neoplastic disease by radioisotope placed inside or
13 close to tumors because brachy means close distance;
14 therapy means treatment. That's the definition
15 currently. However, if you just use the words
16 "brachy" and "therapy," it means treatment from a
17 close distance and therefore, in the broad definition
18 of brachytherapy you can have treatment of disease by
19 sources, not necessarily radioactive, by sources
20 placed inside or close to the tumor. If we use the
21 broad definition of brachytherapy, what I'm going to
22 present to you is brachytherapy.

23 Now what is an ideal brachytherapy system?
24 Well, you want something that will penetrate to the
25 desired depth ideally and then -- very rapidly. High

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1 energy gamma will be like that. Low energy gamma
2 drops off very rapidly and a beta penetrates and then
3 drops very rapidly but may not penetrate enough in
4 certain circumstances.

5 What about dose rate? Well, you know the
6 cobalt has a long half-life, five years. So the dose
7 rate is almost constant, dropping very slowly.
8 Iridium, then iodine, palladium and cesium drops off
9 very fast. But the ideal would be if when you are
10 implanting it it's not radioactive. Then suddenly it
11 becomes radioactive and then it gives a lot of
12 radiation and then when you want it it drops
13 automatically to zero. That is the ideal
14 radioisotope. So far, we haven't found any ideal
15 radioisotope.

16 Let's see what this Xoft system is. The
17 Xoft system includes an x-ray emission controller,
18 some applicator and a disposable x-ray source. The x-
19 ray controller delivers the power, the electricity,
20 and then it can spread the source to wherever you
21 want. So it can pull it back and forth and then you
22 use the output from conventional brachytherapy
23 planting systems to do your planting.

24 So what is the source? The sources is an
25 x-ray source. But rather than a big x-ray source,

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1 it's a very miniature x-ray source as seen, this is my
2 finger, and it's much smaller than my finger and
3 therefore it can go into a narrow needle. So it's
4 2.2 mm in diameter and it's disposable and it can give
5 up to 50 kV x-ray. So it's not the radioactive
6 source, yet the designed is such that it will closely
7 mimic a -- iridium-192 high dose rate source. The
8 output is 0.6 Gy/min and the treatment time will
9 therefore also be comparable to iridium-192 high dose
10 rate.

11 Currently as the system is being used, it
12 is only being used with the -- so right now, it's very
13 similar to using a mammosite balloon except it has the
14 integral drain and the balloon is radiolucent. So you
15 have better visibility.

16 You have a flexishield. So you can put a
17 temporary shielding over the tumor area and you can --
18 everything is disposable at the end of treatment.

19 I'm not going to go into details of
20 spectral characteristics, but basically you are having
21 x-ray emitted with decay very similar to iridium-192
22 and radiobiological effectiveness or RBE is similar to
23 that for iodine.

24 Here is a very primitive dosimetry of a
25 source from a radiochromic film during -- the dose is

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1 very high at the center and rapidly goes down as you
2 go further from 100 percent here to 50 percent within
3 a couple of -- I think a centimeter and a half or so.

4 Now how do you do it? It's done very
5 similar to those who know mammosite, very similar to
6 the way you do mammosite. The surgeon will put the
7 applicator or the mammosite balloon into the tumor.
8 The only difference is instead of attaching the HDR
9 catheter, you attach the Xofter or the Axxent catheter.
10 You localize the balloon with ultrasound or x-ray and
11 then you treat.

12 The treatment times and the fractionation
13 are exactly the same as that for HDR. Right now,
14 you're giving about 34 Gy in ten fractions, similar to
15 that for breast and right now, it is FDA approved for
16 treatment of mammosite of breast. So the treatment is
17 similar to HDR. The source will step like HDR source.
18 It has a stepping source of 5 to 10 drill positions
19 and takes about 5 to 10 minutes.

20 CHAIRMAN MALMUD: What type of anesthetic
21 is used?

22 MEMBER NAG: You can do it in -- it's the
23 same as mammosite. Some places do it under local.
24 Others will do under general. I mean that part
25 doesn't changed at all.

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1 The treatment control is again very
2 similar to the HDR. It shows where the source is and
3 how many seconds is left and so on.

4 What are some of the radiation exposures?
5 It doesn't require a shielded room because of the low
6 energy x-ray. You can have some type of shielding.
7 At a typical operator's location, it's getting only 15
8 mR without the shielding and when you are applying for
9 the license, you have to provide what your exposure
10 rate is.

11 Quality control. Again, they really have
12 not been totally developed, but they are in the
13 process of being developed using AAPM brachytherapy
14 guidelines.

15 Now the FDA status from FDA, it is "to
16 deliver intracavity or interstitial radiation to the
17 surgical margins following lumpectomy for breast
18 cancer." So right now, the FDA approves only for the
19 use in breast cancer.

20 It is not regulated by the NRC because
21 it's non-radioactive source. There are no special QA
22 guidelines as of now, but they are in development.

23 Some of the advantages of this system is
24 that you can switch it on and off. So remember, I
25 told you that the radioisotope where the isotope has

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1 no radiation suddenly gives a lot of radiation and
2 then stops. Here you have something very close and
3 you are able to mimic that. You can adjust the
4 radiation output. There is very little shielding
5 required. So you don't need a shielded room. You
6 don't need to eliminate any radioactive disposable
7 material. The dosimetry characteristic is similar to
8 iridium-192 afterloader and there is no NRC
9 requirement or there is no consequence of this medical
10 event.

11 What is the clinical future and summary?
12 The non-radioactive source is a major advantage from
13 a radiation exposure standpoint. Currently, this has
14 only started recently, and only two sites have
15 started. They are hoping to have about 30 centers by
16 the end of 2007. Right now, it's approved only for
17 breast and so far as we know there has been no off-
18 label uses. However, I can very easily predict or see
19 that there would be either off-label users or
20 potential for use at other sites. For example,
21 vaginal applicators are being planned. Right now, the
22 sources, the entire system is disposable. If they
23 were to build a reusable source, I think the price
24 would come down even more. But right now, each
25 applicator is per patient.

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1 What are the NRC implications? I would
2 like to compare this system to what existed in
3 external beam with the cobalt-60 external beam linear
4 accelerator, one was radioactive and one was not, and
5 one possibility is that if we make the regulations for
6 radioactive materials too burdensome, very onerous,
7 the licensing too difficult, radiation oncologists may
8 decide not to do brachytherapy if you have a very
9 similar alternative which is less cumbersome. And
10 therefore, we now have something that is a very
11 similar alternative. This had happened before with
12 external beam for cobalt, teletherapy versus linear
13 accelerator and also it is slowly happening that many
14 people are abandoning the possible advantages of
15 brachytherapy by using IMRT which is an external beam
16 which has less regulation. So from the NRC viewpoint,
17 you have to strike a balance between how much
18 regulation you want to do and whether by having too
19 much regulation you are pushing some people out of
20 doing this thing at all.

21 The next applicators I would like to talk
22 about is a new thing called Strontium-90 Ophthalmic
23 Applicator with a disclaimer that I'm not an
24 ophthalmologist. I'm a radiation oncologist. So I'm
25 not going to go into details of ophthalmology. I'll

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1 talk about the details of the radiation component of
2 it.

3 But before that, I must say a few words
4 about what it is used for. So you have to know a few
5 things about what is Age-Related Macular Degeneration
6 or AMD. It's a disease associated with aging which
7 affects the part of the eye, the macula, the central
8 part of the retina in the back of the eye, and because
9 there's a gradual destruction of this, you can end up
10 with losing vision especially in people who are 60
11 years of age or more. And there are two types. One
12 is the dry form and the other is called the wet form.

13 In the dry form which is an early stage,
14 you slowly lose some of the retinal function because
15 the cells in the retina break down and so your central
16 vision is affected. You are able to see the
17 periphery, but not the center. There is really no
18 treatment for that and about ten percent of those
19 patients can go on to what's called wet AMD.

20 In the wet AMD, it's neovascular due to
21 formation of vessels and then there is the abnormal
22 vessel that is growing in the back portion of the
23 retina and that's what's called choroidal
24 neovascularization or CNV and these new vessels, they
25 leak out. Because they leak out, they form fluids

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1 which therefore raise the macula and therefore you
2 cannot see anything at all and then a rapid loss of
3 vision.

4 So with this short introduction to
5 ophthalmology, how can we treat this? There are many
6 ways of treating it, laser, photodynamic therapy,
7 injection of drugs in the eye. I'm not going to go
8 into those details because none of these treatments
9 really cure these patients. They may slow it down,
10 but then they continue to lose the vision.

11 Now why would you want to use radiation in
12 the eye? What is this choroidal neovascular cell? In
13 many ways, they are similar to cancer cells because
14 they rapidly proliferate. They are similar to things
15 like neointimal hyperplasia in coronary artery or
16 pterygium in the front part of the eye, and ionizing
17 radiation has proven beneficial in keloids and
18 pterygium and in the intracoronary sight and
19 therefore, if you can destroy these newly forming
20 blood vessels you may be able to stop wet AMD.

21 So Neovista came up with this strontium
22 applicator which basically, I think is an offshoot of
23 strontium-90 intracoronary techniques. There used to
24 be intracoronary strontium-90 for the heart. It's a
25 handheld device, very narrow, and it delivers the

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1 radiation directly to the macula by surgeons who do
2 surgery and place the tip of this right at the site
3 where there is the neovascular formation which will
4 push the strontium into the area, tip it for the
5 required amount of time and pull it back.

6 Technical details, you don't need to know
7 except that it's the source of 357 megabecquerel.
8 Treatment time is on the order of four to five
9 minutes. The dose in the center of that area is 24
10 gray and by the time you go to about 5 mm, you're down
11 to about 7 gray.

12 Radiation protection, you have a rapid
13 fall-off and it's a beta emission so there's very
14 little radiation to the operator.

15 There is a multi-channel tester where you
16 place the applicator before you place it on the
17 patient so it can be verify what the dose rate and so
18 on is.

19 In case you are interested, here is the
20 dose rate profile, 24 Gy given to the center and then
21 16 Gy and 12 Gy and by the time you come to about 5 cm
22 you are getting down to 4 Gy.

23 It's a minimally-invasive, out-patient
24 procedure done by an ophthalmologist. They do a
25 partial vitrectomy under local anesthesia, give 24 Gy

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1 and you are radiating in about four to five minutes,
2 and the whole procedure takes about 20 to 30 minutes.

3 Clinical trials have been started, and
4 about 90 patients so far have been treated in Brazil,
5 30 in Mexico. They have had some improvement which
6 has been comparable to that by some drugs like
7 Lucentis. If you are adding anti-VEGF, you may even
8 get better results. But they are now entering into
9 phase 3 trial.

10 With the prospective randomized phase 3
11 trial, I think, because they are in California, they
12 are calling it the CABERNET from the wine growing
13 there, Central Neo Vascularization secondary to AMD
14 treated with Beta Radiation Epiretinal Therapy.

15 (Laughter.)

16 MEMBER NAG: And they are randomizing Arm
17 A with the Neovista and Lucentis versus Arm B with the
18 active control, Lucentis alone. They are expecting
19 about 450 patients and there will be about 30 sites
20 worldwide, 20 in the U.S., 10 outside the U.S.

21 Summary, I think this represents a new use
22 for strontium. The technology from what I understand,
23 the technology is very similar to the use of
24 technology of strontium-90 for intracoronary
25 brachytherapy for prevention of restenosis that

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1 Novoste was using. It is a handheld equipment and
2 potentially can be useful for a large segment of
3 patients who have wet AMD.

4 Some of my concerns. Right now, it is in
5 use by ophthalmologists who have very little or no
6 radiation training. There has been very little or no
7 radiation oncology input, and this is similar to
8 intracoronary brachytherapy in the early days when the
9 pathologists were doing it without any input. But
10 then once they sought the help of the radiation
11 oncology and the physics team and the dosimetry and so
12 on, the understanding rapidly multiplied and
13 intracoronary brachytherapy flourished.

14 The other concern I have is that the
15 radiation is almost used like a burning tool because
16 in ophthalmology they are more used to using the
17 laser. So they are using it more like a burning tool
18 rather than a radiation tool. The dosimetry right now
19 is very primitive and it is, I think, a very useful
20 technology that may die away if there is inadequate
21 multi-disciplinary input.

22 So my recommendation is that we need to
23 develop a team approach with ophthalmology, radiation
24 oncology, radiation physics and radiation safety being
25 involved. We need to develop guidelines for written

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1 directives, regularly prescribe the prescription
2 points, the dosimetry. And in terms of regulation, I
3 would say it's similar to strontium-90 for
4 intravascular brachytherapy. Therefore, at least,
5 initially regulate under 35.1000 and that the T&E
6 should be similar to that for 35.490. And an
7 authorized user should provide written directive
8 before the use of this teletherapy material.

9 I think with that I'll stop.

10 CHAIRMAN MALMUD: Thank you.

11 MEMBER NAG: I think I finished in about
12 12 minutes.

13 MS. WASTLER: You did very good.

14 MEMBER NAG: Within my time.

15 MS. WASTLER: You're keeping us right on
16 schedule.

17 (Off the record comments.)

18 CHAIRMAN MALMUD: You're on.

19 DR. HOWE: Dr. Nag, when you're looking at
20 this device, do you see it in training and experience
21 to be a three year residency program type of training
22 or do you see it more on the training that we hour-
23 wise --

24 MEMBER NAG: I need to know which of the
25 three things you are talking about.

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1 DR. HOWE: The last one, the strontium-90.

2 MEMBER NAG: Yes, I would say as I said
3 from my standpoint I would think this is similar to
4 the use of strontium-90 like the Novoste. What were
5 you requiring for the use of the Novoste? I think the
6 parallel is the same.

7 DR. HOWE: So you don't see a parallel
8 with the current ophthalmological radiotherapy?

9 MEMBER NAG: No, I should have added that.
10 I'm sorry. It is not similar to the strontium-90
11 applicator that is placed on the surface of the eye.
12 That's entirely different. I think the parallel is to
13 strontium-90 intracoronary application in the heart
14 where, I think, the best way you can develop this
15 technique would be to have a multi-disciplinary team
16 that would include radiation oncology who would be the
17 authorized user, the ophthalmologist who would be the
18 surgeon putting it in, the radiation physicist who
19 would do the dosimetry and radiation safety.

20 CHAIRMAN MALMUD: Other questions or
21 comments? I'm sorry.

22 MEMBER THOMADSEN: We're in the process of
23 putting together our team and getting people educated
24 for this.

25 MS. WASTLER: For which one?

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1 MEMBER THOMADSEN: For the last one. The
2 one the discussion is about right this second.

3 MS. WASTLER: Okay.

4 MEMBER THOMADSEN: And as we're doing so,
5 it's not entirely clear what the radiation oncologist
6 is going to be doing here since the prescription
7 doesn't change. They aren't really in a position to
8 evaluate whether the patient is a good risk or not
9 since it really doesn't have to do with the system
10 such as with the liver and the microspheres.

11 I mean, we're definitely having the
12 radiation oncologists involved, but they're asking
13 what are they going to do. What is their point in all
14 this? So the authorized user is actually a bit
15 superfluous in this whole process.

16 MEMBER NAG: Actually, that was similar to
17 what intravascular cardiology what's happening. They
18 said "Well, you are giving 8 Gy and that's all you
19 need to do." However, I think it requires someone
20 with understanding of different dose, different dose
21 rates. How do you know that 24 Gy is the right
22 amount? Where do you prescribe it to? Is this too
23 much? Is this too little?

24 This fine-tuning, I think, is where you
25 are going to need the radiation oncology. I don't

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1 think you necessarily need the radiation oncology just
2 to be present and give out 24 Gy for every case, but
3 in terms of understanding. Most non-radiation
4 oncologists do not necessarily understand the nuances
5 of what's happening with the dose follow-up, where is
6 the dose, what does the epithelium need and, you know,
7 the dose. The three dimensional dosimetry is
8 something that needs to be worked upon.

9 CHAIRMAN MALMUD: Follow-up questions?
10 Dr. Thomadsen.

11 MEMBER THOMADSEN: I was going to agree.
12 During some sort of clinical trial and the research
13 fine-tuning, you do need everybody on the team and
14 certainly you need somebody who knows something about
15 dosimetry to figure out what's actually going on here.
16 But in equilibrium once people know what the dose
17 should be, it doesn't seem like they're going to be
18 using different doses based on anything with the
19 patient presentation. At that point, it's not clear
20 that the team is all that necessary anymore than it
21 was clear that team was necessary who was
22 intravascular at that point which we never got to that
23 point with the intravascular.

24 MEMBER EGGLI: The question you might ask
25 is why you never got to that point with intravascular

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1 brachytherapy because the interventional cardiologist
2 didn't really like this team approach and they found
3 something else they could do and not have to use the
4 team and they used drug-eluding stents instead and
5 intravascular brachytherapy died very quickly because
6 the interventional cardiologist found this team
7 approach to be cumbersome and if this is a good
8 therapy, I think that your point is well-taken that we
9 should determine what is the role of the various team
10 members for what fraction of time and if it's a
11 valuable therapy you don't want to see it wither on
12 the vine because, in fact, the team approach is
13 cumbersome.

14 CHAIRMAN MALMUD: Donna-Beth.

15 DR. HOWE: Just two quick points. One,
16 intravascular brachytherapy may be down, but it's not
17 dead. The Novoste product was bought by Bess
18 Intravascular. So they are still in the market.

19 And I guess the issue in here is, and
20 we're very interested in hearing the debate between
21 the ophthalmologist with a small amount of radiation
22 training because he's the one that understands the eye
23 and the radiation oncologist who has the extensive
24 training but is not fine-tuned on the very minute
25 places where you have to treat within the eye. So

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1 we're very interested in hearing this discussion to
2 figure out what to do with it because it is coming
3 down now.

4 MEMBER NAG: I think that was very similar
5 for eye plaques. In eye plaque, you don't need a
6 radiation oncologist to place the eye plaque in.
7 There are manufacturers. But for the eye plaque to
8 have come up for treatment of choroidal melanoma by
9 radioactive eye plaque it needed that team approach
10 between ophthalmologists, radiation oncologists and
11 radiation physicists. So I think you need that team
12 approach to be able to understand the whole gambit.

13 CHAIRMAN MALMUD: Dr. Williamson.

14 MEMBER WILLIAMSON: I think there are with
15 different types of brachytherapy procedures the
16 different team members have varying levels of
17 importance and dominance. I think the eye plaque is
18 a very good example where the dominant team members
19 are, in fact, the ophthalmologists and the physicists
20 who puts the thing together and works with the
21 ophthalmologist to interpret the imaging information.
22 There is still, I think, though a role for the
23 radiation oncologist in evaluating the dose
24 distribution and arguing with the ophthalmologist
25 about using it to treat tumors too close to the optic

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1 nerve. So you miss and there are judgment issues
2 where the radiation oncologist can be involved.

3 I think a more nuanced approach than that
4 developed by the FDA for intravascular brachytherapy
5 maybe needs to be considered for this therapy where
6 the level of involvement is more proportionate to the
7 contribution. So I should think that we shouldn't
8 reflexively insist that the radiation oncologist be
9 physically present at every one of these procedures.
10 I'm not sure that played a very useful role in
11 intravascular brachytherapy for coronary restenosis
12 except maybe early on in the first few procedures, but
13 I think that was a major issue in preventing the cost-
14 effective dissemination of the treatment because
15 radiation oncology really wasn't staffed to provide
16 the instant service that was needed to make this be
17 useful on a large scale. So I think one can have the
18 team approach and do it in a way that respects or is
19 proportional to the -- specifies the roles of the
20 individuals in a way that is proportional to their
21 potential contribution.

22 CHAIRMAN MALMUD: Dr. Suleiman.

23 MEMBER. SULEIMAN: I think the team
24 approach can only work as well as the team members can
25 get along.

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1 (Laughter.)

2 MEMBER. SULEIMAN: I found the
3 presentations all fascinating. I found the x-ray
4 source interesting. I think, the CRCPD and the
5 agreement states, I don't think you are going to go
6 unregulated, but I think how it all plays out.
7 Clearly other factors like reimbursement will play
8 into this, but I have no clue how -- I think you sort
9 of see how this thing is going to play out clinically,
10 but it's interesting technologies.

11 CHAIRMAN MALMUD: Let's see. I think next
12 was Ralph.

13 MEMBER LIETO: I actually just had a
14 question for Dr. Nag or Dr. Thomadsen. Does the dose
15 vary per patient or is it just a set absorbed dose
16 that's given for each treatment?

17 MEMBER NAG: Right now, this is a starting
18 technology. I don't think anyone knows what the
19 different doses are. So right now, for starting off,
20 they are giving 24 Gy for all comers. But I think
21 that is where you need someone who understands the
22 differences and therefore for further development 24
23 Gy is what we are doing today. That may not be the
24 optimum dose.

25 So I think you need somebody with more

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1 detailed understanding of the radiation part. The
2 ophthalmologists are great at localizing, knowing,
3 where the different layers of the eye. That's why I
4 was talking about a team approach.

5 MEMBER LIETO: How is this physically
6 placed?

7 MEMBER NAG: Yes. It's like a -- needle.

8 MEMBER LIETO: -- needle.

9 MEMBER NAG: I think it's 20 to 22 gauge
10 needle.

11 CHAIRMAN MALMUD: We have a member of the
12 public who wishes to say something.

13 MS. FAIROBENT: Lynne Fairobent, AAPM. I
14 just want to follow up a little bit on the Xoft System
15 just to make sure the record's complete, although it's
16 not going to be an NRC regulated device. There are
17 actually two systems. There is the Xoft Axxent System
18 and then the Intervene by MediTech is also out there
19 and the Intervene System actually has already been
20 used in over 1,000 cases worldwide, whereas the Xoft
21 System is truly just coming to fruition, I will put it
22 that way, in this country.

23 AAPM recently did provide to CRCPD
24 officially draft suggested state regs. that does cover
25 the QA/QCs, and CRCPD is now working on incorporating

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1 AAPM's recommendations into suggested state regs. and,
2 Orhan, just on your point of whether these will play
3 out in the financial world, Xoft already has a CMS
4 reimbursement code.

5 MEMBER NAG: You are correct, having both
6 the Xoft System and the Intervene System. The reason
7 why I chose not to present the Intervene System is
8 twofold. One, Intervene has been around for awhile
9 and secondly, Xoft is very similar to the HDR. It has
10 a stepping source. It means it goes through a very,
11 very narrow needle. So for all practical purposes,
12 it's in parallel to HDR, whereas the Intervene System
13 doesn't have that much of a similarity to the HDR. X-
14 ray shows it doesn't step in one place.

15 MS. FAIROBENT: Right. I just wanted to
16 be sure they realize there was also a second device
17 that is on the market and is being used in addition to
18 the Axxent System.

19 CHAIRMAN MALMUD: Yes. You were next.

20 MS. FLANNERY: Okay. Thank you. Dr. Nag,
21 going to the strontium-90 ophthalmic device, your
22 presentation was very timely because we do now have
23 two licensees that are interested in using this
24 device.

25 I guess just for the benefit of the ACMUI

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1 I just wanted to quickly read. We do have a section
2 of the regulations that address the other types of
3 ophthalmic devices and as far as the regulations, it's
4 35.491 and there are three sections. One of them is
5 the training which requires 24 hours of classroom and
6 laboratory training and it lists the topics. The
7 other part is the supervised clinical experience and
8 the regs. require five cases and then there's a
9 written attestation.

10 I guess my question for you is would these
11 regulations be applicable to this new device and be
12 specific to that device or you were talking about
13 35.1000. I'm just really interested in ACMUI's input
14 if we had to just sort of start from scratch in
15 developing regulations specific to this device and
16 what kind of training and experience does ACMUI think
17 is necessary for this new device?

18 MEMBER NAG: I think I should have given
19 what a strontium superficial eye applicator is. 491
20 refers to the use of strontium-90 as a surface
21 applicator on the eye. So I don't think the two have
22 any parallel. I think the two -- the word "strontium-
23 90" is the same and using the eye the same, but the
24 technology is so far different from each other, I do
25 not think that the strontium-90 Novoste should be

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1 regulated under the 35.491 because it's so different.
2 That is why my suggestion was to put it under 35.1000.

3 MEMBER EGGLI: What is the --

4 CHAIRMAN MALMUD: I think Dr. Welsh was
5 next.

6 MEMBER WELSH: I would agree that perhaps
7 the best category for this at this time is 1000, and
8 I would also state that I think a team approach is
9 justified here and radiation oncology does have a role
10 at this early stage.

11 The dose is quite large. We're not
12 talking about a few cGy. We're talking about 24 Gy
13 and that dose may change with the clinical experience.
14 As was mentioned, right now it's a single dose, but I
15 would not be surprised if next year some patients
16 would get 20 Gy. Some get 24 Gy. Some might get
17 more. Similarly to vascular brachytherapy, right now
18 there's one isotope. Next year, there might be
19 another if this proves to be of clinical benefit.

20 Overall, it seems that with greater
21 radiobiological understanding, dosimetry
22 understanding, the role of the radiation oncologist is
23 going to be more important.

24 CHAIRMAN MALMUD: Thank you. Dr.
25 Williamson.

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1 MEMBER WILLIAMSON: What dose rate and
2 distance is the 24 Gy administered?

3 MEMBER NAG: Okay. The 24 Gy is
4 administered in about four minutes, within four and
5 five minutes. So you can divide it to be about 6 Gy
6 per minute. At the center, it's like about -- I had
7 it in one of the earlier slides. So it's within like
8 about 1 cm or so and then by the time you come to 5
9 cm, it's down to 4 Gy.

10 CHAIRMAN MALMUD: Sandi.

11 MS. WASTLER: I think while we've heard
12 from you that at least Dr. Nag believes that 35.491 is
13 not applicable to the training and experience for
14 that, it's not applicable to the new technology, what
15 I didn't hear was any views with regards to what the
16 committee believes would be applicable. Is it
17 comparable to any other procedure? Would we compare
18 it to a 290? A 490? A 690? I mean, where should we
19 go?

20 MEMBER NAG: My suggestion was the
21 intravascular strontium-90 for Novoste. I think there
22 are so many parallels.

23 MS. WASTLER: Similar to the dose.

24 MEMBER NAG: Similar to the Novoste was my
25 suggestion. But I would like to hear the other

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1 people.

2 CHAIRMAN MALMUD: We have a member of the
3 public.

4 MR. METZGER: Yes. Bill Metzger. I
5 happen to be from the company that made the strontium-
6 90 devices and we are working with the radiation
7 oncology community right now in answering a lot of
8 these questions.

9 But when this was first envisioned, it was
10 actually considered to be close to the pterygium
11 device mainly because the thing that the
12 ophthalmologist is adding is the surgical technique to
13 get it to a different surface. They're not adding
14 anything in the way of application of radiation. But
15 they are adding the fact that it's direct
16 visualization while it's in place which is very
17 accurate. I mean, they're holding this device in the
18 exact correct position for a non-cancerous lesion for
19 exactly four minutes, and we have ways of measuring
20 whether or not they are capable of doing it.

21 CHAIRMAN MALMUD: Two.

22 MR. METZGER: One hundred percent of them
23 are able to do it.

24 MEMBER THOMADSEN: Despite my disparaging
25 the role of the radiation oncologist in this in

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1 equilibrium, I would in answer to your question in the
2 beginning until the questions are answered and this
3 comes into equilibrium, I would say the suggestion for
4 the qualifications would be just the same as any
5 brachytherapy. That is being a regular radiation
6 oncologist having gone through --

7 MEMBER NAG: 490 basically.

8 MEMBER THOMADSEN: Yes, all the residency
9 and everything. That may be subject to change once
10 all the questions have been answered.

11 MS. WASTLER: And that's the, I should
12 say, the advantage of making it a 1000 where we would
13 --

14 (Telephone interference.)

15 MS. WASTLER: Okay. Reference back to the
16 490 and then as the procedures advance or more
17 experience is gained then we can go back in and say,
18 "Okay, we found out we were too restrictive" or maybe
19 we'll find out we're not restricting them enough. But
20 we can change it as we move forward and get more
21 experience. But as a starting point, you would
22 recommend the 490.

23 CHAIRMAN MALMUD: Dr. Howe.

24 DR. HOWE: I'm wondering if because we do
25 have another authorized user and that's in ophthalmic

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1 therapy that if we put it in 1000 we consider two
2 training paths. One is something similar to the 491
3 which may take over in the end and then the 490 would
4 then be part of a team.

5 It is a high dose rate type of device and
6 so in our model in high dose rate is that the
7 authorized user has to be physically present and that
8 there is an authorized medical physicist physically
9 present. So if you provide training and I don't know
10 if the hours but the actual training may be slightly
11 different for 491 could eventually take the place of
12 having to have a radiation oncologist physically
13 present during the entire procedure if we used an HDR-
14 type of model where this is my dose rate. I'm just
15 throwing that out as a thought.

16 (Telephone interference.)

17 MEMBER NAG: If the 690 had a few other
18 things in it so, although you could use some of the
19 things from 690, you can't use 690 whole scale.

20 DR. HOWE: That's true.

21 MEMBER NAG: Because of all the
22 calibration of HDR, blah, blah, blah. So I think for
23 the time being my suggestion of using intravascular,
24 everything that you did for intravascular
25 brachytherapy strontium-90 of Novoste, if you apply it

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1 here, you don't have to reinvent the wheel at least
2 for the time being.

3 DR. HOWE: We had the physical presence of
4 the authorized user and the medical physicist for the
5 intravascular brachytherapy.

6 MEMBER NAG: For the time being, I think
7 you can do that.

8 CHAIRMAN MALMUD: Dr. Thomadsen.

9 MEMBER THOMADSEN: Was that not changed so
10 that it had to be either at one point, that they both
11 did not have to be present anymore?

12 MEMBER GILLEY: Yes.

13 MEMBER NAG: Yes. It started with one and
14 then as --

15 MEMBER THOMADSEN: It started with both of
16 them having to be and then one or the other.

17 MEMBER NAG: And then once there was more
18 experience gained and people had a comfort level it
19 became either or. I mean, I think similar things
20 could be applied here. You start with both. Once the
21 team has enough experience, you can decide whether you
22 need both or not.

23 DR. HOWE: But it sounds to me like we
24 might have a third person and that would be the
25 ophthalmologist.

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1 MEMBER NAG: Yes.

2 DR. HOWE: Getting training and experience
3 to eventually become an authorized user.

4 CHAIRMAN MALMUD: We have another member
5 of the public with a comment as well.

6 MR. REED: I'm Craig Reed. I'm a health
7 physicist and I was involved with the intravascular
8 brachytherapy development and I'm listening to the
9 discussions about qualifications of users and I look
10 back on our history with the team approach and other
11 things and discussions of people being present or not
12 present and I think this is an early technology and
13 it's going to go through its clinical trials and it's
14 going to go through a very rigorous review process,
15 both with regulators, FDA and NRC. I think we should
16 take the opportunity to learn and see during the
17 clinical process who adds what to the procedure.

18 And certainly to Dr. Nag's point early on,
19 we need to involve everybody who has the most
20 information about all potential effects of the
21 radiation, not just the primary effect of treating
22 this disease, but what are the secondary effects. So
23 I think it's kind of early to decide what the final
24 authorized user will be because we don't really know
25 even really the final outcome and what the potential

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1 side effects are.

2 But what I would say is that I think if I
3 had to make an evaluation of what's an adequate
4 training for an authorized user, I don't know that
5 anybody in 24 hours or 24 days would take in the full
6 scope of the regulations and their impact of
7 everything you need to do be an authorized user
8 especially if you're at a single facility.

9 But with respect to simply using a device
10 that's very precise and very specific in its
11 positioning and localization and how it's used
12 according to a very specific protocol and in a
13 clinical trial or even after a clinical trial, I don't
14 think it's too difficult to imagine that an
15 ophthalmologist who already positions needles and
16 applicators and things at a very precise distance
17 couldn't do that on a regular basis even with a
18 radioactive source.

19 So I think we have to look to the basis
20 for why there are regulations for ophthalmologists
21 using sources close to the eyes that involves 24 hours
22 of training and when that was promulgated years ago,
23 is that still applicable to what we know today. So I
24 also don't think necessarily the training experience
25 we put on an oncologist who treats so many different

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1 diseases throughout the body in so many different
2 organs, that that's appropriate. So we have to find
3 a middle ground and I don't think we want to start
4 necessarily at the most extreme, at least anticipating
5 what would be the final user. Maybe in the clinical
6 trials there's one thing, not in the final end
7 analysis.

8 There was also a comment about having an
9 authorized user present. Well, I assure you that the
10 ophthalmologist is immediately present and can
11 withdraw the source immediately if there's an issue.
12 So there is somebody there who is authorized to put it
13 in and take it out. I'm not too concerned about that
14 type of scenario.

15 Let's assume for a minute that one
16 physician will be treating this patient in the end.
17 All right. What does that physician need to know to do
18 it completely and adequately? Early on, we can
19 consider the team approach, but we have to look
20 towards this being a successful procedure and what's
21 adequate for the full scope of one procedure.

22 CHAIRMAN MALMUD: Thank you. The hour
23 being what it is. I think the next item on the agenda
24 is Ashley Tull and thank you again, Dr. Nag.

25 MS. TULL: Okay. The first thing I want

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1 to go over is the proposed meeting dates for the next
2 meeting, and I have two weeks proposed, October 23,
3 24, 25 and the second one is November, 6, 7 and 8.
4 Does anyone know of any conflicts right now with those
5 dates? Sally.

6 MEMBER SCHWARZ: Sixth, 7th and 8th.

7 MEMBER NAG: Can you give those dates
8 again? October?

9 MS. TULL: October 23rd, 24th and 25th.
10 So we could either do it Tuesday/Wednesday or
11 Wednesday/Thursday.

12 MEMBER FISHER: November 6th.

13 MS. TULL: Yes. November 6th, 7th and 8th
14 is the second set.

15 MEMBER SCHWARZ: That's the one I have a
16 conflict with, the November 6th, 7th and 8th.

17 MS. TULL: What was that?

18 MEMBER SCHWARZ: I won't be available.

19 MEMBER FISHER: I have a conflict also.

20 MS. TULL: Okay.

21 MEMBER EGGLI: I have a potential conflict
22 on the November date.

23 MS. TULL: So three potential conflicts on
24 the November date?

25 CHAIRMAN MALMUD: Any conflicts in

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1 October?

2 (No response.)

3 CHAIRMAN MALMUD: Go for October.

4 MS. TULL: Okay.

5 MS. FLANNERY: I just want to remind
6 everybody that there is the ASTRO meeting to consider.

7 MEMBER NAG: ASTRO is from 27th through
8 31st of October. So it's immediately following the
9 meeting.

10 MS. TULL: Right. I've gotten around that
11 and I also based on the availability of this room. So
12 we don't get bumped to NIH or the Marriott.

13 CHAIRMAN MALMUD: And so Tuesday and
14 Wednesday of that last week in October?

15 MS. TULL: So October 23rd and 24th.

16 CHAIRMAN MALMUD: Okay.

17 MEMBER NAG: I would suggest earlier in
18 the week because if you're having it the 23rd and
19 24th, people cannot finish up the backlog and then go
20 to ASTRO because ASTRO will be starting on the 27th.

21 CHAIRMAN MALMUD: You prefer
22 Monday/Tuesday?

23 MEMBER NAG: Yes. So that it gives you a
24 couple of days to catch up on your work.

25 CHAIRMAN MALMUD: Monday/Tuesday okay?

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1 MS. WASTLER: We checked availability for
2 the room.

3 MS. TULL: Room conflict is fine. So I'll
4 come in on Sunday.

5 (Off the record discussion.)

6 MS. TULL: Starting on the 22nd. Okay.

7 (Off the record comments.)

8 CHAIRMAN MALMUD: Monday/Tuesday.

9 MS. TULL: Monday/Tuesday, October 22nd
10 and 23rd.

11 MS. WASTLER: Okay.

12 MS. TULL: Okay. That takes care of the
13 first thing. Next, I'm going to go through the
14 recommendations that I was able to take notes of. So
15 hopefully, I captured all of them. If you think of
16 something else, feel free to stop me.

17 Dr. Williamson, let's see. The first was
18 with regard to Air Kerma Strength versus activity and
19 ACMUI recommended that the NRC draft an information
20 notice.

21 MEMBER WILLIAMSON: In collaboration with
22 the AAPM.

23 MS. TULL: In collaboration with the AAPM.
24 Okay. So draft an information notice in collaboration
25 with the AAPM.

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1 The next that I have are the 11 issues
2 that were documented during the T&E discussion. Four
3 of those the ACMUI made a recommendation on and the
4 remaining seven will be discussed at a future telecon.

5 Quickly, the first issue was a preceptor
6 statements and the recommendation was to remove the
7 attestation from the board certification pathway.

8 The second issue was impasse to the
9 effective date for previously board certified to be
10 grandfathered and the recommendation to fix that is
11 previously board certified members be grandfathered.

12 The third one is 200 hours of radiation
13 safety training for 390 users under the alternative
14 pathway and the recommendation is to change 200 hours
15 to 120 hours.

16 The fourth issue is the Canadian issue and
17 no recommendations for anything else that I'm going to
18 list here, but the Canadian issue, compatibility,
19 grandfathering, diplomates, preceptor not being
20 available, RSO requirements, seven year recency of
21 training and the unintended consequences of
22 prescriptive requirements and increased complexity
23 with no additional benefit. Those would all be
24 discussed at a future meeting.

25 MS. WASTLER: It would be a teleconference

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1 meeting?

2 MS. TULL: A teleconference.

3 MS. WASTLER: And we will have to get back
4 to you on setting up a date for that.

5 CHAIRMAN MALMUD: Yes.

6 MS. WASTLER: And finding appropriate
7 times.

8 MEMBER SCHWARZ: Can you send a summary of
9 what you've just said?

10 MS. TULL: Sure.

11 MEMBER SCHWARZ: Email?

12 MS. TULL: Yes. Actually, the way this is
13 done, there is an official memo that goes to Dr.
14 Malmud with all of this. It's something that's always
15 been done for the meetings. I don't know if everyone
16 gets a copy.

17 CHAIRMAN MALMUD: No, we don't.

18 MS. TULL: Okay. Would that be something
19 we can do?

20 MS. WASTLER: We could easily send you
21 that.

22 MS. TULL: Yes. I mean --

23 MS. WASTLER: For every meeting there's a
24 summary.

25 MS. TULL: Yes, I did the last one.

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1 Basically, it's just action and then what the NRC is
2 doing or has done.

3 MS. WASTLER: It just goes through a list
4 either motion or action or commitment that's been
5 made.

6 MS. TULL: If you'll look in your binder,
7 the one from the previous meeting is there. So you
8 would see something similar to that.

9 CHAIRMAN MALMUD: I thought the whole
10 committee was getting that.

11 MS. TULL: I think we just sent the memo
12 from Sandi to you, but I can send it to the entire
13 committee.

14 MEMBER WILLIAMSON: I think we only see it
15 in the packet when we come to the meeting.

16 MS. WASTLER: Right.

17 MS. TULL: Correct.

18 MS. WASTLER: Okay. We can send it, but
19 it's under the tab of meeting summary and action
20 items.

21 MS. TULL: Yes.

22 MS. WASTLER: And basically that's --

23 MEMBER WILLIAMSON: As well as a summary,
24 it's a meeting minutes as well. Right?

25 MS. TULL: Correct. There are meeting

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1 summaries and there's the transcript. But as far as
2 action items and motions, there is a specific memo
3 that I will draft that will go from Sandi to Dr.
4 Malmud.

5 (Off the record comments.)

6 MS. WASTLER: Yes. So we will make sure
7 you get that.

8 MS. TULL: Definitely.

9 MEMBER EGGLI: We had a long discussion
10 about the use of the word "competence" in the
11 preceptor in the alternative pathway which the
12 preceptor isn't drafted. Did we make a recommendation
13 on that or did we just have a long discussion and not
14 make a recommendation on that?

15 MS. TULL: Preceptor, remove.

16 MS. WASTLER: It was remove attestation
17 from board certification pathway and change competency
18 to has met the minimum training and experience
19 requirements.

20 MEMBER EGGLI: Okay. So there is a
21 comment for the alternative pathway on competency.

22 MS. WASTLER: Yes.

23 MEMBER EGGLI: Okay.

24 MS. TULL: Sorry. I'm trying to very
25 briefly summarize.

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1 MS. WASTLER: She's trying to summarize
2 them very quickly.

3 MEMBER EGGLI: Yes, I'm just thinking
4 about putting my name on the line again.

5 MS. TULL: And all of these can be
6 discussed again at the future team meeting discussion.

7 MS. TULL: Okay. So moving on past that
8 were potential changes to 10 CFR 35. Five motions
9 were made and all of these were tabled. So if you
10 want me to go through them I will.

11 CHAIRMAN MALMUD: No.

12 MS. TULL: But I feel like they're tabled.
13 Okay. Next, allowing multiple RSOs on a license,
14 ACMUI recommends --

15 MEMBER WILLIAMSON: Wait a minute. Excuse
16 me. I don't think that all the motions were tabled.
17 We passed several of them and then tabled the
18 remainder.

19 DR. HOWE: The first one, they did not
20 pass. Most of the others they passed and then we
21 started tabling.

22 MS. TULL: Donna-Beth, you're not on the
23 microphone.

24 CHAIRMAN MALMUD: The court transcriber is
25 rising his hand and asking us to identify ourselves.

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1 Am I correct?

2 DR. HOWE: Yes. Dr. Howe.

3 MS. TULL: Microphone.

4 CHAIRMAN MALMUD: Microphone.

5 DR. HOWE: Dr. Howe. The first one the
6 ACMUI did not support. Then they supported and I
7 don't have my notes in front of me.

8 MS. WASTLER: 35.2.

9 DR. HOWE: And then they tabled.

10 MS. TULL: I have it in front of me, but
11 if we want to go through them we can.

12 MS. WASTLER: We do. 35.2 motion was
13 leave as is. All right. 35.12 was moved and
14 approved. 35.50(c)(2) moved and approved. 35.50(d)
15 moved and approved. 35.57(a), hang on, tabled.

16 CHAIRMAN MALMUD: Tabled. That's where we
17 got --

18 (Several speaking at once.)

19 MS. WASTLER: And then 35.75 was tabled.

20 DR. HOWE: Tabled.

21 MS. TULL: And then there was a final
22 recommendation.

23 MS. WASTLER: Everything else was tabled.

24 MS. TULL: And then Dr. Nag made a
25 recommendation to table all of the issues so that

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1 ACMUI could gather --

2 CHAIRMAN MALMUD: No.

3 MS. WASTLER: Only those left.

4 CHAIRMAN MALMUD: Only those remaining
5 issues.

6 (Several speaking at once.)

7 MS. TULL: Sorry.

8 MS. WASTLER: No, that's fine. That's why
9 we go through the action items.

10 MS. TULL: Okay.

11 MS. WASTLER: So we make sure that we have
12 those clear and understood.

13 MS. TULL: Yes. This will be much easier
14 to put together once I have the actual transcript.

15 CHAIRMAN MALMUD: Sure.

16 MS. TULL: To see what the wording of the
17 motion is.

18 MS. WASTLER: Right.

19 MS. TULL: Okay. So moving on past Donna-
20 Beth's presentation to microspheres.

21 MS. WASTLER: Did you do the RSO?

22 MS. TULL: I started the RSO.

23 MS. WASTLER: Yes. Go through that.

24 MS. TULL: Okay. So there was a
25 recommendation from ACMUI to allow multiple RSOs on a

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1 license and one RSO can be identified as the one in
2 charge. ACMUI recommended that NRC publish an RIS
3 after receiving input, review and comments from the
4 agreement states and ACMUI. Does that sound
5 acceptable?

6 MS. WASTLER: Okay.

7 MS. TULL: Next is the microspheres. As
8 far as written attestation, there was a motion to
9 delete the paragraph and add "and provide
10 documentation" to the second paragraph of the
11 guidance.

12 Team approach, there was a motion to
13 replace the term "oncology" with "individual with
14 expertise in cancer treatment or management."

15 MS. WASTLER: There was also a motion
16 under the written attestation to add the requirement
17 -- I'm trying to remember it.

18 MS. TULL: From 690.

19 MS. WASTLER: For 690.

20 MS. TULL: The wording from 690.

21 MS. WASTLER: The wording from 690.

22 MS. TULL: Correct. Okay. On the other
23 slide that I had which was specific medical use,
24 licensees and waste disposal, approved both of those
25 changes. ACMUI recommended to approve both of those

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1 changes and then the dose versus activity was tabled
2 for further discussion at the next teleconference or
3 future meeting and then there was also one thing on
4 the slide that we didn't get to and that was a
5 clarification that we're asking for as far as end of
6 the treatment, end of the procedure. We need a
7 recommendation from you on that as well.

8 MS. WASTLER: We didn't get to it.

9 MS. TULL: We didn't get to it, but it's
10 tabled.

11 MS. WASTLER: Okay. Next. Sentinel
12 lymph node. A recommendation was made that after
13 injection and an imaging is done, the subsequent
14 surgery should not be regulated by NRC.

15 CHAIRMAN MALMUD: I think we were a little
16 more specific than that. We were indicating that we
17 felt that they were two separate procedures and
18 therefore, we didn't feel that was within our purview.

19 MS. TULL: Okay. I will go back to the
20 transcript and pull the wording from that.

21 This wasn't a motion but this happened.
22 We moved items 17, 18 and 19 which was the Elekta
23 Perfexion, Dr. Welsh's AU approval for byproduct
24 material and Michelle Burgess' NMED presentation to a
25 future meeting.

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1 And on -- I guess that's it. There was no
2 formal recommendation from Dr. Nag's presentation.

3 MS. WASTLER: But we will go back and
4 double check the transcript for any additional action
5 items.

6 MS. TULL: Yes, once I get that.

7 MS. WASTLER: And we will -- As Ashley
8 noted, we will put that together and we'll make sure
9 that all members get a copy of that.

10 MEMBER SCHWARZ: Great.

11 MS. TULL: Okay. Next on my list, time
12 and travel. If you haven't already turned it in to me
13 with signatures, please do.

14 Self-evaluations are in the front of your
15 binder. Please fill those out. Give those to me as
16 well.

17 CHAIRMAN MALMUD: I'll have to mail those
18 to you.

19 MS. TULL: Okay. You can mail them to me
20 or if you would like, I can send you the Word version
21 and you can just respond electronically.

22 CHAIRMAN MALMUD: Yes, can you send the
23 Word version?

24 MEMBER WILLIAMSON: That would be good.

25 MEMBER EGGLI: That would be excellent.

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1 MS. TULL: I'm all about electronic.

2 (Off the record comments.)

3 MS. TULL: I have been sending everything
4 in Word. So I think that that's -- We're
5 transitioning in our office.

6 MS. WASTLER: We're actually transitioning
7 to Word. We're finally coming into the 21st century.

8 (Off the record comments.)

9 MS. WASTLER: It's going to be traumatic
10 for all of the staff.

11 MS. TULL: If you want to leave your name
12 tags, I'd appreciate it because then I wouldn't have
13 to reprint them. It would save me some time next.

14 MS. WASTLER: And I would just like to say
15 on your desk you will find copies of the most recent
16 regs. Those are yours, should you chose to carry them
17 back. That is your copy to take with you.

18 And I think last I just wanted to thank
19 everyone. We really appreciate your contribution and
20 I just wanted to again extend Janet's apologies for
21 not being here, though I'm sure you all understand.
22 She had a medical treatment that she's trying to
23 recover from was not able to be here, but she just
24 wanted us to extend her -- Yes. She had a myelogram
25 and was not, shall we stay, has had a whopping

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1 headache and if it didn't stop, I think she went back
2 in to get it, I guess, redone so it would -- leaking.
3 Not pleasant at any rate. So she's been not feeling
4 well.

5 MS. TULL: 5:01 p.m.

6 CHAIRMAN MALMUD: One final word. I want
7 to thank --

8 MEMBER WILLIAMSON: 5:02 p.m.

9 MS. WASTLER: Okay.

10 CHAIRMAN MALMUD: I'm sorry. I wanted to
11 thank all of you, all the members of the committee and
12 all the staff for two very intense days with lots of
13 very animated and robust discussion. I think that
14 everyone here certainly has exhibited their commitment
15 to getting this done in the best interest of patient
16 care and we appreciate the effort. Our opinions may
17 vary at times, but our goal is the same and it's
18 wonderful to work with you all.

19 MEMBER NAG: And we survived.

20 CHAIRMAN MALMUD: We survived. Yes.

21 MEMBER WILLIAMSON: I think we respect the
22 way you've run the committee.

23 CHAIRMAN MALMUD: Thank you very much.
24 And we're going to miss you, Jeff.

25 MEMBER WILLIAMSON: Yes, maybe things will

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1 be less robust.

2 (Laughter.)

3 CHAIRMAN MALMUD: There may be fewer
4 words, but also you have done some yeoman's work for
5 us in various presentations that you've made which
6 represent an extraordinary amount of effort and I
7 don't want you to think that we don't remember that
8 don't appreciate it because we do and you will be
9 missed.

10 MS. WASTLER: I would second that. Thank
11 you very much.

12 (Applause.)

13 MS. WASTLER: And with that, we close the
14 meeting, Dr. Malmud.

15 CHAIRMAN MALMUD: Safe trip everybody.

16 MS. WASTLER: Thank you.

17 CHAIRMAN MALMUD: Off the record.

18 (Whereupon, at 5:02 p.m., the above-
19 entitled matter was concluded.)

20

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