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UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

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MEETING

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OPEN SESSION

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THURSDAY,

APRIL 21, 2005

+ + + + +

ROCKVILLE, MARYLAND

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The committee met at the Bethesda North
Marriott Hotel and Conference Center, 5701 Marinelli
Road, at 10:00 a.m., Leon S. Malmud, Chairman,
presiding.

COMMITTEE MEMBERS:

- LEON S. MALMUD, M.D., Chairman
- DAVID A. DIAMOND, M.D., Member
- DOUGLAS F. EGGLI, M.D., Member
- RALPH P. LIETO, Member
- SUBIR NAG, M.D., Member
- ALBERT E. RAIZNER, M.D., Member

1 SALLY WAGNER SCHWARZ, R.Ph., Member

2 ORHAN SULEIMAN, Ph.D., Member

3 WILLIAM VAN DECKER, M.D., Member

4 RICHARD J. VETTER, Ph.D., Member

5 JEFFREY F. WILLIAMSON, Ph.D., Member

6

7 NRC STAFF PRESENT:

8 THOMAS H. ESSIG, Designated Federal Official

9 CHARLES L. MILLER

10 IVELISSE CABRERA

11 TRISH HOLAHAN

12 DONNA-BETH HOWE, Ph.D.

13 ANGELA R. McINTOSH

14 RANDY RAGLAND

15 RONALD ZELAC, Ph.D.

16

17 ALSO PRESENT:

18 DOUGLAS KONDZIOLKA, M.D., IRSA

19 DAVID LARSON, M.D., ASTRO

20 MICHAEL A. SHEETZ, University of Pittsburg

21 GERALD A. WHITE, M.S., AAPM

22 PAUL WALLNER, ASTRO

23

24

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

(10:15 a.m.)

CHAIRMAN MALMUD: If I may call the committee to our next session, so that we can hopefully stay on schedule. Dr. Williamson, in recognition of his interest in being a discussant of this next issue, has asked me to chair this session for him, which I am willing to do so that we'll get started as soon as everyone is seated and the subject is an update of Redefining Medical Events. This is an open session and we will discuss the NRC's -- with the NRC staff the ACMUI's recommendations regarding updated a definition of a medical event in 10 CFR Part 35.

Dr. Williamson?

MEMBER WILLIAMSON: Well, it might be helpful if we returned to the document that was sent out some weeks ago before which had been patched together by Ralph and myself by going through the transcripts which listed every item that the subcommittee had voted on and come to consensus on. It might be useful, I think, to start with to go through that and determine, you know, which items need to be rediscussed so we have kind of a clear idea of where we are. So I would suggest that for your

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1 consideration.

2 CHAIRMAN MALMUD: Please do.

3 MEMBER WILLIAMSON: Is that agreeable to
4 everybody?

5 CHAIRMAN MALMUD: Dr. Nag?

6 MEMBER NAG: Now, those are not in the
7 handouts, are they?

8 MEMBER WILLIAMSON: They're not in your
9 handout. This is the document that predated the
10 report that you made. It was very short. It had kind
11 of a summary of medical event -- of our actions over
12 the last three months.

13 MEMBER NAG: All of us may not have that.
14 How are we going to follow you?

15 CHAIRMAN MALMUD: Who has a hard copy
16 here? Ralph, can we borrow that and have it copied?

17 DR. SAKIERA: Excuse me, are we talking
18 about the one that's labeled "Recommendation ACME
19 Subcommittee on Medical Event Criteria"?

20 MEMBER WILLIAMSON: It's entitled "Summary
21 of 8th March 2005 Meeting Recommendations
22 Incorporating Ralph Lieto's Review of Transcripts".

23 CHAIRMAN MALMUD: Is that in the book?

24 MEMBER WILLIAMSON: I don't believe that's
25 in the book.

1 MEMBER DIAMOND: No, this is different, I
2 believe.

3 MEMBER WILLIAMSON: What is in the book --

4 CHAIRMAN MALMUD: It's dated March 24th.

5 MEMBER WILLIAMSON: What is in the book is
6 a six-page double spaced writeup entitled
7 "Recommendation of ACMUI Subcommittee on Medical
8 Criteria". It's got task of subcommittee, members,
9 method and summary of recommendations.

10 MEMBER NAG: Yeah, that's the one that I
11 made. He's talking about the one that he made earlier
12 than mine.

13 MEMBER WILLIAMSON: Then I would prefer we
14 go to that one which is based on detailed review of
15 the transcript because, you know, as it's turned out,
16 Dr. Subir has some issues, I think important ones,
17 that he wants to raise about the different consensus
18 points. So what I can do is put it on this drive and we
19 can project it if you'd like.

20 CHAIRMAN MALMUD: Thank you.

21 MEMBER WILLIAMSON: So I will proceed to
22 do that but to get an idea of where we are and what we
23 need to do and see if we can uncover the basis, the
24 objective basis of you know, these differences and
25 determine whether we can come to a resolution I think

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1 would be a useful exercise. So I am not having any
2 luck getting it to stay on here.

3 CHAIRMAN MALMUD: Ralph, do you have a
4 hard copy?

5 MEMBER LIETO: Yes, I do.

6 MEMBER WILLIAMSON: I could connect my
7 computer to this projector and project it if you like.

8 CHAIRMAN MALMUD: Sure.

9 (Pause)

10 MEMBER WILLIAMSON: Okay, so these were
11 the recommendations that we had adopted on March 8th,
12 2005. This was with the participation of the ACMUI
13 sort of as an extension the subcommittee, so this one.
14 "Any permanent implant is an ME excluding seed
15 migration and patient intervention if; A, the total
16 source strength implanted anywhere in the patient
17 exceeds the written directive by more than 20 percent
18 or; B, the total source strength implanted in the
19 target volume deviates from the written directive by
20 more than 20 percent".

21 So I think that that it would be helpful
22 to know the disagreements with this and basis of them.

23 MEMBER NAG: Why don't you go ahead. I
24 think what I'd like to do when we do the explanation,
25 one of the problems I felt in the subcommittee meeting

1 on the phone, it's hard to explain some of the things
2 and so I had prepared some slides here that will
3 explain with a diagram, you know, some of the reasons.
4 Otherwise, we have people on the phone saying well,
5 maybe, you know -- you know, it's hard to explain some
6 of the things. So why don't we go ahead and --

7 MEMBER WILLIAMSON: Okay, but let's
8 identify anyway, it is Part B you disagree with but
9 not Part A or both?

10 MEMBER NAG: Well, basically, if we can --
11 I had mentioned in my letter you have in your handout,
12 if you say that the -- if the total source strength,
13 again, instead of saying target volume, we already
14 have the words the implant site in the 10 CFR Part 35.
15 I had one thing here about what Part 35 had here and
16 if I can go to my wording, it would be -- well, that's
17 why I want to -- I had my slide in there and why don't
18 you go ahead.

19 MEMBER WILLIAMSON: Well, I just -- the
20 whole purpose for going through these is to find out
21 where there is disagreement and where not, so --

22 MEMBER NAG: Again, what do you mean by
23 target volume?

24 MEMBER WILLIAMSON: Okay.

25 MEMBER NAG: When we had it that the

1 target volume, you say implant site and leave it as
2 implant site, like it is now, you know, you cover the
3 tumor area or, you know, what the area you want to
4 implant. The target would be, you know, people in --
5 people have different definitions of the target and
6 you know, therefore, you already have implant site
7 there. Why not keep it as implant site?

8 MEMBER WILLIAMSON: So the word target
9 volume and --

10 MEMBER NAG: Yeah, because lab target
11 volume, clinical target volume, there are so many
12 different kinds of many target volumes. The second
13 thing was the -- in -- if you are saying that the it's
14 a variation of more than 33 percent, that will cover
15 that definition of medical event. You do not have to
16 add that total source strength implanted anywhere in
17 the patient because if you have added a certain number
18 of millicuries, say, into the area, then if you are
19 adding 20 percent more than that, you have what you
20 exceeded the 20 percent. So I know that you're
21 dealing with that. If someone is saying that they
22 have less number of seeds in the target, they keep on
23 adding more and other sources can go anywhere else,
24 but you know, you are saying that you have already
25 given a certain number of source strength in the area,

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1 if you add more, that is automatically included. So
2 by saying --

3 MEMBER DIAMOND: Let him respond. Let him
4 -- so you heard what Subir said. Do you have any
5 particular thoughts regarding the language that he
6 proposes?

7 MEMBER WILLIAMSON: Well, I thought -- my
8 suggestion was we just go through and I think Subir
9 wants to present a detailed set of slides on this
10 matter.

11 MEMBER DIAMOND: The same slides as
12 yesterday or different slides?

13 MEMBER NAG: Many of them are different,
14 many of them --

15 MEMBER WILLIAMSON: Well, should we --
16 would it be the preference we just continue --

17 MEMBER NAG: Continue and we finish.
18 Because of lack of time we --

19 MEMBER DIAMOND: To me it's a very
20 straightforward issue. We all are trying to describe
21 something. We're pretty close. Subir's point is that
22 by changing two words, it could go and simplify that
23 particular paragraph and I'm just asking, Jeff, do you
24 see a particular problem with that revised language,
25 or proposed language, excuse me?

1 MEMBER WILLIAMSON: What's the proposed
2 language? Maybe you could restate it just in one
3 sentence Subir, what you propose.

4 MEMBER NAG: Okay, do you all have your
5 handout with the --

6 (Pause)

7 MEMBER NAG: If you look in your handout,
8 page 3, the words at the send of the second paragraph,
9 after discussion you can put the -- it will be very
10 simple and it will be very similar to the current
11 wording that is there already in Part 35 and just
12 change it slightly as I will read, "A medical event
13 results if the total source strength implanted into
14 the treatment site differs from the prescribes source
15 strength by 20 percent or more". So just the wording
16 like that would be very similar to the way it with
17 currently except that "those" the word "those", would
18 be replace by source strength. So it will not require
19 any major alteration except for that those.

20 Now, the other thing is that in the
21 permanent implant you can have some of the seeds that
22 migrated so in addition to that we just say, "It is
23 not considered to be a medical event if the deviation
24 resulted from basic intervention or due to seeds that
25 were implanted in the site but subsequently migrated

1 outside the treatment site". This wording was also
2 taken from Part 35, so basically it would not require
3 any major change.

4 MEMBER DIAMOND: Do you want to respond?

5 MEMBER WILLIAMSON: Yeah, I guess my
6 concern was the situation where a substantial number
7 of seeds were implanted in the wrong site but the
8 number -- the amount of activity implanted in the
9 treatment site or target volume, which I have no
10 strong feelings what word we use --

11 MEMBER NAG: But then --

12 MEMBER WILLIAMSON: Can I finish my
13 sentence, please? Okay, my concern was the case where
14 the activity implanted in the treatment site agreed
15 within 20 percent with the original written directive,
16 but there was an additional component of activity that
17 was implanted in some volume or tissue outside of the
18 treatment site and since the proposal, global proposal
19 is to delete the wrong site criterion, my argument was
20 that the new definition of medical event must include
21 some provision to capture as medical events those
22 administrations in which a significant portion of
23 activity was implanted in an unintended site or organ.

24 MEMBER NAG: Basically, that will be
25 automatically part because then you are either

1 implanting into that -- you are saying you implanted
2 those seeds and you didn't mean that. Then you're
3 implanting into that -- it is a medical event or you
4 have implanted into a different organ which is then
5 along side. So that is automatically part and
6 therefore, the A, becomes superfluous. That was my --

7 MEMBER DIAMOND: Jeff, could you give us
8 a hypothetical example in which you could construct a
9 medical event in your opinion which would not be met
10 by the definition that Subir is proposing?

11 MEMBER WILLIAMSON: Yes, I will try.
12 Suppose a written directive were written to say 80
13 seeds of half millicurie are to be placed in the
14 prostate or periprostatic tissues and the physician is
15 in the process of doing this implant and all of a
16 sudden discovers on ultrasound that he has implanted
17 or she had implanted 40 seeds in the bladder by
18 mistake or 40 seeds in the tissue below the apex and
19 says, "Oh, dear", and then mid-course in implant
20 corrects that, takes 80 additional seeds and implants
21 them properly in the target organ, that would be, you
22 know, an example.

23 CHAIRMAN MALMUD: Al?

24 MEMBER RAIZNER: Sometimes the less you
25 know, the clearer things are but in the plan, the

1 treatment prescription, you're listing the treatment
2 site, so why not leave -- why not leave anywhere in
3 the patient out and leave into the treatment site out
4 and just have it read "the total source strength
5 implanted exceeds the written directive"? You have a
6 written directive that tells you how much you're going
7 to implant and where. And if you exceed that by 20
8 percent, that's a medical event.

9 You don't have to repeat the treatment
10 site. You don't have to repeat in the patient. You
11 don't have to repeat it. You've already designated
12 where that dose is supposed to -- where that activity,
13 where that source is supposed to go. In other words,
14 make that even simpler that --

15 MEMBER DIAMOND: So, Subir, Jeff just gave
16 us a good -- an example. The practitioner is doing an
17 implantation. The practitioner mistakenly puts 50
18 percent of the initial seeds into the wrong site. He
19 recognizes it in real time, adds on. How would that
20 fall into your construct?

21 MEMBER NAG: Well, in that case, you have
22 implanted 40 seeds without a directive, because your
23 directive was the implant site and you have implanted
24 that 80 millicuries to the implant site. You have
25 implanted X number or 40 other seeds. Either you are

1 saying that, "I have implanted 120 millicuries", which
2 is possible, or you are saying, "I have implanted the
3 80 millicuries to the right site", but the 40
4 millicuries were implanted without any written
5 directive. I mean, it's the same as saying -- when
6 you are saying you're taking an I-125 infusion.
7 You're infusing X number of millicuries.

8 You say, "I'm infusing X number of
9 millicuries". And then you say, "Well, I've got so
10 much with the thyroid I want to infuse more. The
11 total amount that you are infusing or you're injecting
12 or you're implanting, is the total number of
13 millicuries you put in. You can't say, "I only put in
14 30 millicuries, those other 40 millicuries I put in
15 were not -- were not part of the directive". I mean,
16 you have to -- you know, you have to direct in total
17 how much you put in.

18 MEMBER WILLIAMSON: The one concern --

19 CHAIRMAN MALMUD: Dr. Suleiman?

20 MEMBER SULEIMAN: Mine is a simple
21 question, I think. Okay, as the physician is -- as
22 they're going in to implant, they're doing it with
23 ultrasound. The target volume is what they are going
24 to see during the procedure, right? They haven't done
25 a conform map ahead of time. So how can you -- so if

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1 in the best opinion of the medical doctor they, in
2 fact, implanted these in the appropriate area, by
3 definition that's the target volume. They wouldn't
4 intentionally put them outside what they consider a --

5 MEMBER NAG: No, they don't intentionally
6 put it outside, but again, I think when I show you
7 some of the slides, of how the implant volume works,
8 you know, what do you mean by -- what do you mean by
9 target volume, what do you mean by implant site, what
10 do you mean by margin and I think some of these things
11 may become a little more clear.

12 MEMBER SULEIMAN: But again, I'm confused.
13 Are we really discussing medical medicine here where
14 you've got some tolerance and ability to choose and
15 select or are we clearly aware that you're outside a
16 boundary where you shouldn't be?

17 MEMBER DIAMOND: What we're doing is
18 actually we're very, very close and Jeff's concern is
19 that the definition that Subir proposes may allow a
20 few things to fall through the crack. Whereas Subir
21 feels that his proposed language is adequate. How's
22 that? We're very close.

23 MEMBER WILLIAMSON: Yeah, that's accurate.
24 We don't think we need to question the fundamental
25 basis of this approach. We all agree on it and we

1 will submit it. You know, you guys can vote it down
2 if you don't like it, but I think it's not helpful to
3 start questioning the basis of it at this point. We
4 need to get beyond this little disagreement.

5 Could I say a comment back to -- I
6 understand, you know, a little bit, you know, what
7 your proposal is. It seems it's almost kind of very
8 legalistic. We are so close to agreeing on the
9 essence of this thing. You know, my concern is if you
10 take that point of view that we have to put in place
11 an implicit or explicit rule that any seed which is
12 implanted in any organ must have a written directive,
13 that would also be destructive, because as I
14 understood it was felt by you and Dr. Diamond that you
15 needed some wiggle room in order to put certain number
16 of seeds in tissues outside of the target volume in
17 order to achieve good coverage and you know,
18 accommodate all of these variations we've been talking
19 about. And so I think by taking your position, you
20 would hamper your flexibility in doing that because
21 you'd require then a separate directive for --

22 MEMBER NAG: No, not really.

23 MEMBER WILLIAMSON: -- more wiggle room.

24 MEMBER NAG: No, not really. We did --
25 you know, I describe all of these in detail because

1 the people who are doing it, we felt it would be safer
2 that way because by putting treatment site, you, you
3 know, designate the area of where you want to implant.
4 Someone might want to implant that area plus some
5 margin. You know, it would still allow that part of
6 the implant site. Where if you're implanting totally
7 a different organ all together, it will not be an
8 implant site. So it will take care of people who are
9 implanting totally absurd areas whereas people who are
10 implanting the prostate and the margin just around
11 that may include some of the adjacent organ would be
12 included.

13 CHAIRMAN MALMUD: Dr. Nag, do you think
14 that it would be clear to those of us on the committee
15 to first listen to your slide presentation?

16 MEMBER NAG: That is what I had suggested.

17 CHAIRMAN MALMUD: And how long -- how many
18 slides do you have? How long would that take?

19 MEMBER NAG: It depends on, you know, how
20 much questions we will have. You know, if I have no
21 questions --

22 CHAIRMAN MALMUD: How many slides?

23 MEMBER NAG: -- then it goes faster. If
24 there are questions, then --

25 CHAIRMAN MALMUD: If there are no

1 questions, how many slides do you have?

2 MEMBER NAG: Probably about 25 slides.

3 MEMBER DIAMOND: I think we can get by
4 without this. Let me say how I view this because I'm
5 just a simple country doctor. I like simple things.
6 When I write my -- when I phrase my work directive, I
7 don't write as a treatment site prostate. I'll write
8 prostate PTV, planting target volume, because when I
9 design these implants, depending on what the
10 particular clinical factors are, I'm asking my
11 dosimetrist and my physicists to help me design a
12 margin around that and that, by definition, will
13 include some of the base of the bladder, the
14 extraprostatic tissue, seminal vesicles occasionally.
15 So to me I think that in just about every case I can
16 think of, that by phrasing the treatment site that
17 way, we would probably be able to get by with Subir's
18 more simple definition.

19 And I'm concerned that when a community
20 reads the definition that you have in front of you,
21 they're not going to understand what it means. The
22 only scenario that would present a problem would be
23 the situation that Jeff gave as a hypothetical, where
24 someone clearly has done something far beyond the PAL
25 and is basically going back to cover his or her tracks

1 by doing that. But for 99.999 percent of the
2 instances, I think that the more simple language would
3 cover it. That's a personal opinion.

4 CHAIRMAN MALMUD: Dr. Vetter.

5 MEMBER VETTER: Even simpler is Al's
6 suggestion, why won't that work, which basically was,
7 "Any permanent implant is a medical event excluding
8 seed migration and patient intervention if the total
9 source to strength implanted exceeds the written
10 directive of more than 20 percent", period.

11 MEMBER NAG: What about the decrease which
12 is why we have the deviants.

13 MEMBER VETTER: Okay, deviates, I'm sorry.

14 MEMBER NAG: Deviates.

15 MEMBER VETTER: Deviates.

16 MEMBER NAG: Yeah, which is what I had
17 suggested that the total source strength.

18 MEMBER VETTER: But his definition left
19 out total body, it left out target volume, it left out
20 all of that.

21 MEMBER WILLIAMSON: Well, you could put it
22 in the big toe then, instead of the prostate and not
23 have a medical event. Part of the problem that we're
24 struggling with is NRC has been confronted with a
25 bunch of cases where a large fraction of the seeds was

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1 implanted in an adjacent organ and so I think we've
2 all accepted as a common group that we have to have a
3 criterion that distinguishes those cases and I would
4 submit that probably is a very tiny percentage of the
5 practicing physician population but nonetheless, we
6 have to have a criterion that covers egregious
7 implantations in -- you know, that any reasonable
8 medical practitioner would say is a substantial
9 deviation from clinical intent.

10 MEMBER DIAMOND: But, Jeff, outside of the
11 hypothetical that you gave us, if you go back to the
12 cases that we looked at a year and a half ago, two
13 years ago, wouldn't each of those cases have fallen
14 into the medical event definition as proposed. I
15 think they would.

16 MEMBER WILLIAMSON: They probably would
17 but what if, you know, I think it is nonetheless an
18 important hypothetical that you know, people do make
19 simple stupid errors like they could start suturing --
20 this isn't a permanent implant but start suturing an
21 eye implant to the wrong eye. They have given
22 implants to the wrong patient, so, you know, really
23 simple stupid things can happen and that constitutes
24 the --

25 MEMBER DIAMOND: But again --

1 MEMBER NAG: Wrong site, the wrong site --

2 CHAIRMAN MALMUD: I'm sorry, gentlemen.
3 We cannot be -- Ms. Nang, will have difficulty
4 following you. Dr. Diamond, do you want to finish
5 your statement?

6 MEMBER DIAMOND: No, we're discussing
7 different hypotheticals and again, just my feeling is,
8 is that all of these different scenarios that I've
9 heard of probably would be met by the definition just
10 proposed.

11 CHAIRMAN MALMUD: Excuse me, Dr. Diamond,
12 which definition do you refer to, the one that's
13 labeled on the screen as March 8th or the January
14 18th. Which would --

15 MEMBER DIAMOND: I'm referring to the one
16 labeled March 8th and I'm referring to the one as
17 rephrased by Dr. Vetter a few moments ago.

18 CHAIRMAN MALMUD: So it's March 8th with
19 the change in the March 8th indicating that any --
20 I'll read it. "Any permanent implant is a medical
21 event, excluding seed migration and patient
22 intervention, if a total source strength implanted
23 anywhere in the patient varies from the written
24 directive by more than 20 percent." Is that --

25 MEMBER DIAMOND: Correct.

1 CHAIRMAN MALMUD: And varies, it take
2 "exceeds" or "is under". Now, I've read it. It
3 doesn't mean that we've approved it. I just read it.
4 Dr. Nag, you indicated disapproval of what I just
5 said.

6 MEMBER NAG: Right.

7 CHAIRMAN MALMUD: And how do you disagree
8 with it?

9 MEMBER NAG: Well, not anywhere in the
10 place is in the implant site because you cannot --
11 because then I would say, well, I want to implant
12 anywhere in the patient including the head or the --
13 no, it is into the implant site, which is the same
14 definition that I gave.

15 CHAIRMAN MALMUD: Therefore, you would
16 read it as follows; if I may, quote, "Any permanent
17 implant is a medical event, excluding seed migration
18 and patient intervention, if a total source strength
19 implanted in the target -- in the patient".

20 MEMBER NAG: The treatment site, the
21 treatment site.

22 CHAIRMAN MALMUD: "In the treatment site"?

23 MEMBER NAG: Right.

24 CHAIRMAN MALMUD: All right, is that
25 wording agreeable to you, Dr. Diamond and to you Dr.

1 Williamson, "treatment site"?

2 MEMBER DIAMOND: That's fine with me. It
3 is redundant because a written directive does include
4 a treatment site but if that makes them happy, that's
5 fine.

6 CHAIRMAN MALMUD: All right, so then we
7 will say -- I'll start again, "Any permanent implant
8 is a medical event, excluding seed migration and
9 patient intervention, if a total source strength
10 implanted in the treatment site in the patient varies
11 from the written directive by more than 20 percent",
12 period.

13 MEMBER NAG: That is exactly the same
14 wording that I have.

15 CHAIRMAN MALMUD: Therefore you would --
16 excuse me.

17 MEMBER NAG: The only difference is that
18 with that excluding in the middle, then the language
19 becomes a little harder to understand which is why the
20 wording here was the written intervention was put in
21 the next sentence. That was the only difference.

22 CHAIRMAN MALMUD: Thank you, but you --

23 MEMBER NAG: So basically, we agree.

24 CHAIRMAN MALMUD: Do you agree with what
25 I just read?

1 MEMBER NAG: Yes, I did except that the
2 language is a little -- you know, although I'm not I
3 primarily English speaking person, that language is a
4 little --

5 CHAIRMAN MALMUD: Awkward.

6 MEMBER NAG: Awkward and I had to, you
7 know, basically make some language change.

8 CHAIRMAN MALMUD: Dr. Diamond, do you
9 agree with the spirit of what was just read?

10 MEMBER DIAMOND: I'm a happy man.

11 CHAIRMAN MALMUD: And Dr. Williamson, do
12 you?

13 MEMBER WILLIAMSON: No.

14 CHAIRMAN MALMUD: And how do you disagree
15 with the awkward statement I just read?

16 MEMBER WILLIAMSON: Ralph has been
17 patiently waiting.

18 CHAIRMAN MALMUD: Ralph?

19 MEMBER LIETO: As another member of the
20 subcommittee, I have a question and maybe I know the
21 answer already for Dr. Diamond in terms of
22 terminology, when Dr. Potters was on the
23 teleconference, my distinct impression from him and
24 from the transcript was that the terminology of
25 planned target volume was -- would account for

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1 different physician determinations of the treatment
2 site. And using that language, was something that I
3 got the distinct impression from him was what should
4 be used in any type of definition that we come up
5 with. Now, my question is, is the terms planned
6 treatment volume and treatment site the same thing?

7 MEMBER DIAMOND: What I would say is this;
8 I would leave it to the individual practitioner what
9 specific terminology to use; number 1, treatment site
10 versus PTV. That's an individual pattern or practice.
11 Number 2, yes, you are correct, a description, a
12 denotation of a planned target volume does vary from
13 practitioner to practitioner and within a given
14 practitioner depending on the patient's circumstances.

15 CHAIRMAN MALMUD: Thank you, Dr. --

16 MEMBER LIETO: Just to follow, would it be
17 more appropriate that in a definition that we're
18 discussing here, with the planned target volume being
19 more general and -- or --

20 MEMBER DIAMOND: Again, I think that by
21 just using the terminology "treatment site", I think
22 that would be adequate.

23 MEMBER LIETO: Thank you.

24 CHAIRMAN MALMUD: Dr. Zelac has been
25 waiting patiently. Dr. Zelac?

1 DR. ZELAC: Thank you. Two things.
2 First, the hypothetical that Dr. Williamson gave as an
3 example is not too far from the reality of a event
4 that we actually had where the intended implantation
5 was approximately -- the numbers may not be quite
6 right, approximately 100 seeds into the prostate and
7 the result was that 30 of those seeds or 40 of those
8 seeds wound up in the bladder.

9 The difficulty with what we're discussing
10 is that under the current rule, the practitioner has
11 the option of completing the written directive after
12 the implantation and what in this case the
13 practitioner did was essentially revise the written
14 directive to say that, "My intent was only to implant
15 70 seeds into the prostate". What they did, of
16 course, was to remove those from the bladder so that
17 they wouldn't have an medical event because of the
18 dose that resulted to the bladder.

19 MEMBER DIAMOND: My response to that would
20 be is that I can't think of language that would
21 protect us against unscrupulous operators.

22 MEMBER NAG: Excuse me. I think we do
23 have -- I do have in my slides meaning about division
24 that we separate from here and that will take care --
25 and the language can we worded such that it depends on

1 what you mean by end of the procedure, and I think
2 that's a separate thing. Again, I think lien to the
3 benefit if I went and showed the slides and then we
4 can all discuss, you know, rather than, you know,
5 coming back -- now we are coming back to the revisions
6 and again, I have slides of the revisions on what you
7 mean by completion of the procedure.

8 CHAIRMAN MALMUD: Thank you, I -- Dr.
9 Zelac.

10 DR. ZELAC: Just to finish up on this
11 particular case, what the practitioner said was, "That
12 was my one treatment", and then he wrote a second
13 written directive to complete the actual intended
14 implantation and that was a separate treatment, to put
15 in the extra 30 seeds later at a separate time.

16 CHAIRMAN MALMUD: Thank you, Dr. Zelac.
17 May I ask you a question? How did that come to the
18 attention of the NRC if that physician was successful
19 in covering his or her tracks?

20 DR. ZELAC: My recollection is that the
21 radiation safety committee reviewed the actions in the
22 clinic and decided that this came under the medical
23 event report and decided to report it.

24 CHAIRMAN MALMUD: And do you know if that
25 was also considered an issue within the hospital's

1 credentialing process?

2 DR. ZELAC: I cannot comment.

3 CHAIRMAN MALMUD: Thank you. We have one
4 more voice to be heard?

5 MR. WHITE: I'm Gerry White. I'm from the
6 American Association of Physicists in Medicine and I
7 would just like to ask you to think very carefully
8 about using the word PTV or planning treatment volume
9 in this medical event plan. It's a very precise
10 definition in ICRU and I do a lot of prostate plans.
11 It's not unusual to plan 10 to 15 percent of the seeds
12 intentionally outside of the PTV and then you're
13 three-quarters of the way to the medical event
14 criteria. So I think that that is probably being poor
15 terminology.

16 MEMBER DIAMOND: So you would agree with
17 the treatment site terminology?

18 MR. WHITE: Treatment site sounds much
19 better. Treatment site is where you want to put the
20 seeds, but PTV could be troublesome.

21 CHAIRMAN MALMUD: Thank you. Could you
22 just amplify that a bit for our edification? If the
23 term "planned treatment volume" means what it says,
24 why would one plan to have 15 percent -- plan to have
25 15 percent outside of the planned treatment volume?

1 MR. WHITE: The planning treatment volume
2 is the volume where the physician would like a
3 particular dose to go. It's often helpful to have
4 some seeds outside of that volume by four or five
5 millimeters in order to pull the dose out just a tad.
6 If you anticipate having the seeds right on the
7 periphery of the PTV, it's not always possible to get
8 the coverage that you would like.

9 CHAIRMAN MALMUD: So the planned treatment
10 volume is a term or art. It doesn't really mean what
11 it would appear to mean to a layman.

12 MR. WHITE: It means where you want the
13 dose to go and one might need to put seeds elsewhere
14 to achieve that.

15 CHAIRMAN MALMUD: Thank you. May we get
16 back to the issue now? We had wording that was --
17 apparently met the needs of Dr. Nag and Dr. Diamond
18 and Dr. Williamson was still concerned about that last
19 version. Can you just remind us of what your concern
20 was, Dr. Williamson, with the last version?

21 MEMBER WILLIAMSON: Yes. My concern is
22 that with a small subset of cases where the written
23 directive is correctly executed within 20 percent with
24 respect to the treatment site or target volume,
25 whatever we want to call it, but there involves

1 erroneous placement of seeds in another organ, you
2 know, that aren't necessary for coverage of the
3 intended target organ. I mean, I think there are, you
4 know, many kinds of other examples on temporary
5 brachytherapy where you would -- where the wrong site
6 criterion can be invoked independently of the accuracy
7 to the target volume component.

8 A good example would be in high dose rate
9 brachytherapy you know, if a vaginal cylinder or a
10 dwell -- basically array of dwell positions is for one
11 fraction or part of the treatment put in a wrong
12 place, say two centimeters away from the vaginal apex,
13 this is detected on the first -- after the first
14 fraction and corrective measures put in place to
15 insure that over the next few fractions the target
16 volume or treatment site gets the correct dose but
17 under current medical event rule, this would still
18 possibly be caught by the separate wrong site
19 criterion. And I think, you know, given what the
20 commissioners have said, that they don't want to -- us
21 to do something that jeopardizes health and safety by
22 letting cases or, you know, horses out of the barn
23 that are currently kept in the barn, I think we should
24 think very carefully because remember one of our other
25 recommendations is to delete as an independent pathway

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1 the wrong site criterion. So you have to be sure that
2 you've built in you know, all possibilities into the
3 primary criterion that you're going to use.

4 MEMBER DIAMOND: To respond to that,
5 again, I think what you're talking about Jeff, is
6 language to help protect against unscrupulous
7 operators. And I stand by my contention that trying
8 to design language to that effect is extraordinarily
9 difficult. To use a farfetched example, of the
10 operator that's implanted -- doing an implant for the
11 prostate and then also goes and puts 25 percent of the
12 initially planned activity into the great toe. Well,
13 as it stands, that operator could go and make a
14 modification to the written directive and say, "I
15 planned to operate the big toe as well". Your
16 language is not going to go and be able to address
17 that as well. And therefore, my point is, we do the
18 best we can with the language but if someone really
19 wants to be unscrupulous, dishonest, whatever, I can't
20 think of language that's going to provide the
21 flexibility that we need for real time modifications
22 and still cover it.

23 MEMBER WILLIAMSON: I agree with you
24 completely that there's no foolproof, bomb-proof
25 system but you know, I would say we make -- the

1 operative word is we make the language as best we can
2 to express the intent of the rule which is everybody
3 agrees the intent of the rule is that you should
4 implant the sources in the intended treatment site and
5 not somewhere else. And so we've done our job if we
6 make the languages the best we can.

7 So I'm arguing why make it less than the
8 best, because it seems to me that the proposal on the
9 table is less than the best. It doesn't clearly
10 describe the underlying intent of the rule which is to
11 preclude egregious implantation of sources in other
12 organs.

13 CHAIRMAN MALMUD: May I ask a question and
14 then -- a question of you? Is there any consensus
15 among the radiotherapists and physicists that there --
16 that it would be worthwhile reporting if more than 20
17 percent of the intended dose goes to another organ?
18 Would you report that normally?

19 MEMBER NAG: What we discussed in our
20 committee was that that is automatically caught by the
21 words if the source implanted in the treatment site is
22 more than 20 percent. So that is already caught
23 because the deviation means 20 percent more or 20
24 percent less. So just the wording automatically
25 catches it if someone is giving 20 percent more

1 because then what is the treatment site? If they're
2 putting X number of millicuries in, and it goes a
3 little bit beyond the treatment site, that whole area
4 is the treatment site, so you are -- there's no need
5 to put both of them. Adding more, 10 to 20 percent
6 more would also be included in the medical event
7 treatment site.

8 CHAIRMAN MALMUD: Your point, Dr. Nag, is
9 that if the target organ were the prostate, and if
10 more than 20 percent of the seeds were incorrectly
11 initially implanted into the bladder, that that would
12 be a medical event because fewer than 80 percent of
13 the seeds would have been implanted in the target
14 organ, the prostate and/or tissue surrounding it,
15 which would be -- which would be included in your --
16 in Part A. That's what you're saying.

17 Is there disagreement with that
18 observation by either Dr. Diamond or Dr. Williamson?

19 MEMBER WILLIAMSON: Yes, I'm disagreeing
20 with the observation. I think it is possible that --
21 and it appears from Dr. Zelac there's been a case that
22 comes close to this where, in fact, the total amount
23 of activity implanted into the patient was
24 substantially more than what was in the original
25 written directive.

1 MEMBER NAG: But then you are
2 automatically rejected it because you have implanted
3 20 percent more into your implant site. That whole
4 area is your implant site.

5 CHAIRMAN MALMUD: Mr. Lieto?

6 MEMBER LIETO: I have a suggestion so that
7 maybe we might go onto the next point.

8 CHAIRMAN MALMUD: Please.

9 MEMBER LIETO: Is that we take these two
10 definitions -- because we're obviously going to have
11 to come back to the committee after we go through all
12 this and either discuss it and vote on this maybe in
13 a teleconference or a future meeting, is that we take
14 these two definitions as proposed by Dr. Nag and Dr.
15 Williamson and you know, have the rest of the
16 committee look at this, digest it, maybe also consult
17 with some of their other colleagues, saying, you know,
18 implementing this in our situation, which of these is
19 going to -- would you think would catch outlying
20 events, and then kind of come back at that. That way
21 we can move onto the next point and --

22 MEMBER DIAMOND: I like the idea of
23 circulating this amongst the professionals.

24 MEMBER WILLIAMSON: I think it's a good
25 idea. Maybe we can find some other options.

1 MEMBER DIAMOND: We're not going to get
2 past this today, so let's circulate it around the --

3 MEMBER WILLIAMSON: I would just ask for
4 one more consideration. Would it be worthwhile asking
5 staff if they have a recommendation for how to cover
6 the incident that was described by Dr. Zelac?

7 MEMBER DIAMOND: In what sense?

8 CHAIRMAN MALMUD: Has any of the NRC staff
9 considered how we should deal with an issue in which
10 a physician appears to have intentionally rewritten
11 his or her directive to cover a misadministration?

12 MEMBER WILLIAMSON: I think that's almost
13 a different issue.

14 CHAIRMAN MALMUD: Isn't that the issue
15 that Dr. Zelac raised? That's the issue that you've
16 raised.

17 MEMBER WILLIAMSON: That's one of the
18 issues. I think the -- well, let me ask you to add
19 onto your charge to the staff, ask them how they would
20 like to see the wrong site issue addressed, because
21 that's how I'd put the question.

22 CHAIRMAN MALMUD: But you see --

23 MEMBER WILLIAMSON: Do they think the
24 wrong site scenario that has been presented is
25 nonsense or not?

1 CHAIRMAN MALMUD: I don't know as that's
2 fair to them. You raised a question. I'll ask Dr.
3 Zelac to respond to it.

4 DR. ZELAC: I think that Mr. Lieto's
5 suggestion is a good one in that we put these two to
6 the side and look at them over time and that would
7 include not only the members of the advisory committee
8 but also the liaison, myself and well as the
9 subcommittee and we will get feedback from staff as to
10 whether we think one is preferable to the other or a
11 merger of the two is more appropriate or any
12 combination thereof.

13 CHAIRMAN MALMUD: Thank you, Dr. Zelac.

14 MEMBER NAG: May I?

15 CHAIRMAN MALMUD: Yes.

16 MEMBER NAG: Remember yesterday when I'd
17 shown some of the slides about the warning dangers --

18 CHAIRMAN MALMUD: Yes.

19 MEMBER NAG: -- many of the things became
20 more apparent than if we had just thought, you know,
21 kept on talking forever. A few slides made a lot of
22 difference, and with that - That was the reason when
23 we were under 10.1.4 we did not have the ability to be
24 able to show some of the visual impressions which we
25 can do in a face-to-face meeting and some of these

1 things -- some of the concepts are easier seen than
2 may be discussed by words.

3 MEMBER LIETO: Mr. Chairman, I would just
4 again emphasize my suggestion because we do not have
5 the privilege of the abundant audio/visual
6 presentation that you have and this would give the
7 opportunity to distribute that audio/visual
8 presentation so that all the members would have it so
9 that if you're making reference to slides or a
10 particular slide, they can have that at their -- you
11 know, in front of them. So again, I'd like to move
12 on.

13 MEMBER DIAMOND: I agree. I appreciate
14 all the time you've spent on this but I don't think
15 it's necessary right now. I think the real issue is
16 not definitions of volumes but trying to get a sense
17 from the different societies can the language be
18 crafted any better to cover these potentialities of
19 unscrupulous operators, period. That's it. I mean,
20 we're in agreement on everything else.

21 CHAIRMAN MALMUD: I have a question.
22 Would it be possible, Dr. Nag, for you to e-mail the
23 set of slides to the participants?

24 MEMBER NAG: Yes.

25 MEMBER WILLIAMSON: I think that's a good

1 idea.

2 CHAIRMAN MALMUD: May I make the following
3 suggestion then? That Dr. Nag e-mail to the members
4 of the ACMUI committee, the whole committee and staff,
5 copies of the 25-slide presentation so that we can
6 read through them, be edified by them and then the
7 process that Dr. Zelac and Mr. Lieto suggested can
8 move forward. Is that acceptable, Dr. Nag?

9 MEMBER NAG: That's fine.

10 CHAIRMAN MALMUD: Thank you. So that will
11 be the next step in the process. Dr. Miller?

12 DR. MILLER: Given that that's the next
13 step, if I could just ask the members and my staff to
14 consider in the thought process another aspect. You
15 heard Commissioner Merrifield, I believe it was,
16 yesterday, discuss a little bit of our obligations to
17 report abnormal occurrences to Congress annually. One
18 of the criteria -- what the staff is currently
19 wrestling with also is, should the abnormal occurrence
20 criteria be changed and if so, how? One of the
21 necessary but not sufficient conditions in walking
22 through the abnormal occurrence criterion is that it
23 is a medical event that, and then there's other
24 criteria.

25 So it's extremely important as -- and

1 we've had a lot of debate on this amongst the staff.
2 It's extremely important that a necessary criteria but
3 not sufficient is that it's a medical event to begin
4 with. So I'm just asking that that be thought through
5 as part of the solution to this problem, not that
6 every medical event results in an abnormal occurrence,
7 but we wouldn't want something that everyone would
8 consider to be an abnormal occurrence eliminated from
9 the process because of the definition of the medical
10 event. Thank you.

11 CHAIRMAN MALMUD: Thank you. Now, we can
12 move onto the next issue.

13 MEMBER WILLIAMSON: Which is Dr. Nag has
14 -- previously we had approved several motions which
15 would redefine the meaning of written directive and
16 place new restrictions on the ability of the
17 practitioner to revise the written directive compared
18 to the current law. Among these changes were a
19 requirement that the written directive be specified in
20 terms of total source strength and number of seeds and
21 absorb dose no longer be an option. And secondly, we
22 specified that the time frame for written directive
23 revisions would be one working day within -- following
24 the completion of the source insertion procedure only
25 for permanent implants.

1 Dr. Nag has the view that the current
2 language of Part 35, as I understand it, already
3 precludes the practitioner from waiting -- from doing
4 the written revisions 30 or 60 days after the
5 procedure. So that is the point to be resolved,
6 whether, in fact, Dr. Nag's claim is true about the
7 existing language.

8 CHAIRMAN MALMUD: Dr. Nag?

9 MEMBER NAG: Okay. Now, about the written
10 directive, in addition to the permanent implant, like
11 one small thing I think we need to note which is that
12 even for removable implants, there are many places
13 that goes right according to source plan. And
14 therefore, the ability to do source plan based
15 prescription should not administered even for
16 removable implant. Again, you see the handout at the
17 end of page 1, or the beginning of page 2, it would
18 mean that many place would say even for removable
19 implant so many milligram hours, yes.

20 MEMBER WILLIAMSON: Well, I think that our
21 primary focus is on permanent implants. We're trying
22 to -- I think that's a good issue. I have -- agree
23 with you, as a matter of fact, but honestly, I think
24 we -- the main focus of our subcommittee is permanent
25 implants and I think it would be helpful to stay on

1 that main point and return to this later under the
2 question, unresolved and undiscussed question, should
3 we extend the mandate of the subcommittee or not.

4 MEMBER DIAMOND: I would just agree on
5 that point. Yes, for the temporary implants we do
6 need to include an activity based approach with
7 milligram rated equivalent hours and I think we can
8 move on from that right now.

9 MEMBER NAG: Okay. Now, in a permanent
10 implant it depends on how you are describing that.
11 Can I just show my slide? It would be a lot easier.
12 Then you can following the wording in the slide. It's
13 here in the handout also but, you know, you can see on
14 the slide the wording. Otherwise, it's very hard to
15 follow which part I'm saying. I mean, the same thing
16 is there on the slides and that's why I felt it would
17 be a lot easier, otherwise, we keep on interrupting
18 and --

19 MEMBER WILLIAMSON: Well, we all have your
20 handout.

21 CHAIRMAN MALMUD: We have your handout.

22 MEMBER WILLIAMSON: I can put up your
23 handout, in fact, on my computer.

24 CHAIRMAN MALMUD: Okay.

25 MEMBER WILLIAMSON: I'm sorry, it's going

1 to take me a minute here.

2 MEMBER LIETO: Mr. Chair?

3 CHAIRMAN MALMUD: Mr. Lieto?

4 MEMBER LIETO: Is the issue that we're
5 addressing right now the point about the one day --

6 MEMBER NAG: Yes.

7 CHAIRMAN MALMUD: Yes.

8 MEMBER NAG: Now the following regulation
9 would say that you are allowed to make modifications
10 or revision during your procedure and you can make a
11 verbal. If you are not able to make a written
12 revision, you can make a verbal revision and within 48
13 hours you can put that verbal revision into written
14 form and sign it. So it allows you to make the
15 revision after you have gotten your implantation but
16 before you have finished the procedure.

17 So the question then comes, when is the
18 end of the procedure? In a removable implant, the end
19 of the procedure is when you pull the implants out.
20 That's easy enough. In a permanent implant, when is
21 the end of the procedure. You have placed the seed
22 and basically, that's the end of the procedure. One
23 can radiate infinitely for the next thousand years
24 basically but the end of the procedure is when you
25 have taken all the needles out and therefore, if you

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1 had to make a revision, you should be making a
2 revision before the alternation of the shape of the
3 tumor or the site of the tumor, you make the revision
4 and we do that.

5 If we find that our implant is larger or
6 the implant is different in shape and size, we give a
7 verbal revision and we say, you know, we have to
8 implant so much more and we sign it afterwards. So
9 therefore, you know, you don't need to add, you know,
10 a 24-hour rule or anything like that because that is
11 already provided that you can make your revision while
12 you're doing the procedure and sign it within 48
13 hours.

14 CHAIRMAN MALMUD: Dr. Diamond, then Dr.
15 Zelac.

16 MEMBER DIAMOND: This is a very, very
17 simple issue. The issue is, are the current
18 regulations for the 24-hour time period appropriate or
19 as Dr. Subir has just mentioned, is there a concern
20 that that language "termination of the procedure",
21 could be construed to the life of a permanent implant,
22 which of course, is infinite? I think any reasonable
23 reading would lead the individual to discern that this
24 is 24 hours after the end of the operative procedure
25 which places the implant and I think that's it.

1 CHAIRMAN MALMUD: Dr. Zelac?

2 DR. ZELAC: The rule that we're operating
3 with now was crafted to recognize that there would
4 have to be modifications of the initial written
5 directive during the procedure based upon the clinical
6 situation. The rule for permanent implants and
7 permanent implants only, was set up so that the
8 completion of the written directive would be after the
9 implantation but before the completion of the
10 procedure, rather nebulous words in terms of how that
11 would be interpreted.

12 The way it has typically been interpreted
13 is that the procedure isn't completed until such time
14 as the final dose determinations have been made.

15 MEMBER DIAMOND: Okay, that's silly.

16 DR. ZELAC: It is silly.

17 MEMBER DIAMOND: Okay, so let the lawyers
18 know that's silly. No --

19 DR. ZELAC: Is anyone from General Counsel
20 present?

21 MEMBER DIAMOND: And no physicist, no
22 radiation oncologist would say otherwise and I think
23 we can just put this to rest.

24 DR. ZELAC: I wish we could but our
25 attorneys say we can't.

1 MEMBER DIAMOND: Well, let them go to
2 medical school, let them --

3 MEMBER NAG: I think the procedure ends
4 when you have left the operating room. It's like
5 saying you're having I-131 injection, the procedure
6 ends when you take out that syringe. Here the
7 procedure ends when you have left the operating room.
8 Any modification you make during the procedure and
9 after that is the end.

10 DR. ZELAC: I'm in complete agreement with
11 you. I mean, you could say when the patient leaves
12 the OR or possibly extended to when the patient leaves
13 recovery or perhaps even possibly extended to when the
14 patient leaves the hospital. But beyond that, to me
15 personally, seems inappropriate but the wording of the
16 rule as we have it now says that it is undefined and
17 on that basis, as I said, it has normally been
18 interpreted to extend as far as when the dose
19 determination is -- the final dose determination is
20 made, which could be a month later.

21 MEMBER NAG: Or never. Some physicians
22 don't do a final dosimetry.

23 DR. ZELAC: Well, at some point, the
24 written directive has to be completed.

25 CHAIRMAN MALMUD: Mr. Lieto?

1 MEMBER LIETO: I would like to make a
2 suggestion to the subcommittee that we come back to
3 the committee with a recommendation something to the
4 effect that the NRC issue a -- this may not be the
5 right vehicle, but a regulatory issue summary that
6 states that for permanent implants -- this way we
7 don't have to go into regulatory space. That for
8 permanent implants, the end of the procedure is
9 defined or is established as being at the end of the
10 surgical procedure or something -- I'll leave that to
11 my colleagues to come up with a better terminology and
12 phraseology but that way we can address this
13 recommendation and not have to go into redefining
14 anything in regulatory space.

15 MEMBER NAG: And I agree and that was my
16 point.

17 CHAIRMAN MALMUD: Mr. Lieto agrees, Dr.
18 Nag agrees. Dr. Diamond, do you agree?

19 MEMBER DIAMOND: I concur.

20 CHAIRMAN MALMUD: And Dr. Williamson, do
21 you agree?

22 MEMBER WILLIAMSON: No.

23 MEMBER DIAMOND: Oh, Jeff.

24 CHAIRMAN MALMUD: Why do you not agree,
25 Dr. Williamson?

1 MEMBER WILLIAMSON: Because I accept the
2 position of the staff that they have taken every
3 reasonable effort to try to do this without a
4 regulatory change. And I believe they are counting on
5 us to help them by providing them, you know, at least
6 a concept they can use for correcting this. You know,
7 and I think it's part of our job to help them and not
8 insist it should be done some other way when for weeks
9 we've been having these meetings. It's been carefully
10 explained to all of you what the legal situation is.
11 We have taken that into account in our prior
12 discussions and consensus, so I must say I'm
13 disappointed in the subcommittee's response.

14 CHAIRMAN MALMUD: Well, normally, I am
15 opposed to new regulations and reinterpretations. On
16 the other hand, of there seems to be a consensus that
17 the existing interpretation is without sense, I think
18 the term silly was used, then I think we owe it to the
19 patient population who is our primary concern and to
20 the NRC whose primary concern is the welfare of
21 patients, we correct what appears to be an error.

22 MEMBER DIAMOND: A question for Tom and
23 Charley. Do you feel that this type of language isn't
24 -- that Ralph proposes is necessary to be included as
25 formal regulatory language or do you feel in your

1 opinion that it could be addressed in guidance or an
2 RIS and the reason again is that the Commissioners are
3 begging us not to do rulemaking change unless it is
4 essential.

5 MR. ESSIG: I mean, certainly we have
6 precedent for a -- and Dr. Zelac can add to this but
7 we have a precedent for a -- where a regulatory
8 framework exists but it lacks specificity, we can
9 clarify the intent of the regulations using generic
10 communication vehicles such as a regulatory issue
11 summary but we cannot promulgate new regulations via
12 that mechanism or add to an existing regulation but if
13 the existing regulation allows for enough flexibility
14 we could do that and maybe Dr. Zelac could add to
15 that.

16 CHAIRMAN MALMUD: Dr. Zelac?

17 DR. ZELAC: I think that there is merit to
18 attempting to do what we all agree is the appropriate
19 thing through the interpretation of what the current
20 regulatory language is and I think that bringing it to
21 our Office of General Counsel for consideration would
22 be the probably appropriate next step. Now, they may
23 come down and say that you are then creating
24 regulation via guidance. If that's the case, then we
25 have no alternative but revising the current

1 regulatory language. It's worth a try, perhaps.

2 CHAIRMAN MALMUD: So we'll -- oh, Dr.
3 Miller?

4 DR. MILLER: With your indulgence, may I
5 question my staff? Ron, do you have any specificity
6 for what OGC finds problematic with the interpretation
7 of the regulation? In other words, OGC reminds us
8 that only the Office of General Counsel can interpret
9 regulations. Is there something in the language of
10 the inter -- the language of the regulation that OGC
11 finds problematic with proceeding with what we're
12 doing?

13 I've heard discussion that it's not
14 specific so what specifically is the objection that
15 we're trying to overcome from OGC?

16 DR. ZELAC: Specifically, the problem that
17 OGC has or sees and understands with the current
18 regulation is that there is no specificity as to when
19 the procedure is completed. The wording says before
20 -- after implantation but before completion of
21 procedure. But when the procedure is done is open.
22 It's clear for all the other modalities when the
23 procedure is over. But for a permanent implant it is
24 not clear. That's the modality to which that
25 extension to completion of the written directive then

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1 applies.

2 Essentially, OGC understands that there's
3 an issue. Personally, I can tell you that OGC, at
4 least the people at OGC with whom I have discussed
5 this matter, think that rule change is probably the
6 only way out but I wouldn't want to speak for them
7 officially in that regard.

8 CHAIRMAN MALMUD: Dr. Zelac, before you
9 leave, may I -- what clinical problem has occurred or
10 could occur that would injure a patient as a result of
11 the current non-specific interpretation of the
12 wording?

13 DR. ZELAC: I think the example that I
14 brought up before which is OGC will look at these
15 issues when an occurrence is brought to their
16 attention and they have to make an interpretation as
17 to whether or not, in fact, something is a medical
18 event or is not. The example that I gave before I
19 think is pretty close to the mark of what you're
20 asking in that we have the situation where the
21 implantation was not conducted as originally thought
22 and intended, perhaps because of poor visualization
23 with the ultrasound during the implantation procedure
24 itself and significant fraction of the total intended
25 implanted activity wound up in the wrong organ.

1 The problem is that under the current
2 regulations we had the opportunity for the
3 practitioner to complete, or if you will, revise the
4 written directive after this occurred.

5 MEMBER NAG: I would --

6 CHAIRMAN MALMUD: The microphone just went
7 dead. I don't think we're broadcasting now. Can you
8 hear Dr. Zelac?

9 DR. ZELAC: Yes, I'm testing the
10 microphone.

11 CHAIRMAN MALMUD: Thank you. Okay, so
12 that there is concern on the part of the ACMUI that in
13 the example that you cited, there is now an
14 opportunity for, if you will, less than optimal care
15 which we believe could be -- that the opportunity for
16 less than optimal care which has already occurred,
17 could be closed if we tighten the wording.

18 DR. ZELAC: There would be a need for the
19 practitioner to complete the written directive by a
20 prescribed time.

21 CHAIRMAN MALMUD: Right.

22 DR. ZELAC: And at that point it would be
23 clear that something either was done as intended or
24 not, or if there was -- but that still wouldn't
25 totally remove the possibility of -- I don't know

1 quite how to say this, but the practitioner who didn't
2 do things as he intended from correcting officially on
3 paper that misadministration, if you will.

4 CHAIRMAN MALMUD: Thank you. Can anyone
5 else cite an example in which there has been an injury
6 to a patient as a result of the current wording which
7 does not describe adequately the termination of the
8 procedure? In other words, what I'm trying to drive
9 at is, is there a need to change the rule when the
10 existing rule hasn't resulted in any harm even though
11 it may not make sense?

12 MEMBER NAG: I would like to ask in a
13 permanent implant with injecting I-131 into the
14 thyroid, you are giving a permanent implant injecting
15 it into the patient and the radiation to the thyroid
16 is going on in that period of time. When is that
17 procedure considered to be over?

18 DR. ZELAC: The procedure is over as soon
19 as the administration has taken place. It does not
20 depend on how long the dose is being delivered. When
21 the injection has been made or the oral dose has been
22 administered, the procedure is complete and that's the
23 way the rule reads. You don't have the leeway for a
24 modification after the administration of the written
25 directive for that modality or for any of the others

1 except for permanent implant.

2 MEMBER NAG: But in permanent implant,
3 there is nothing that says you can modify afterwards,
4 after the treatment process and you know, after the
5 treatment is completed, if that is the definition
6 after the administration is over, after the treatment
7 is completed means, after you put in your last seed.

8 DR. ZELAC: As I've said before, OGC looks
9 at the wording of the existing regulation and
10 concludes that it is unclear as to when the procedure
11 is completed. It's clear from the way the rule is
12 written that after implantation but before completion
13 of the procedure is there and allows the practitioner
14 to make the adjustments to the written directive
15 afterwards, after the implantation.

16 But that's a little off course because the
17 written directive has to be completed at some point.
18 Is it a month after the implantation, is it two
19 months, is it one day, is it one hour? That's what
20 we're talking about.

21 CHAIRMAN MALMUD: Thank you. Dr. Howe?

22 DR. HOWE: I think the difference that we
23 have now, it seems to be a consensus among the ACMUI
24 that completion of the procedure is a definite point,
25 when you leave the OR, when you put all the seeds in.

1 And I think if the ACMUI were to make a recommendation
2 that clarified that there was a consensus and this was
3 your understanding of it, that would have more weight
4 with OGC than the staff.

5 CHAIRMAN MALMUD: Thank you. Dr.
6 Williamson has a comment.

7 MEMBER WILLIAMSON: Yeah, I would -- I
8 think that's all fine and well and I certainly could
9 support that. The difficulty is if you made such a
10 recommendation now, it would conflict with the rest of
11 the rule as written. I would like to remind the
12 subcommittee and ACMUI members that the current
13 definition of medical event is specified in terms of
14 absorbed dose and that involves comparison of the
15 post-implant evaluation to the written directive. So
16 obviously, a recommendation of this kind, given the
17 way medical event and especially wrong site are
18 defined currently in the rule, would be completely
19 inconsistent and it would be, you know, impossible for
20 any kind of a meaningful revision to be written at
21 all. So, you know, I think one of the reasons we
22 embarked on the pathway of a source strength based
23 criterion is because it was consistent with basically
24 revising the written directive at the time of the
25 procedure because the physician would have all of the

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1 information available to do a meaningful activity
2 based prescription revision but not a dose based one.

3 CHAIRMAN MALMUD: Dr. Nag.

4 MEMBER NAG: Yeah. I'm telling you, Jeff,
5 I do not understand your objection. We have already
6 said that dose based prescription would not work for
7 permanent implant and we are making it source strength
8 based. So if that is so, what does your objection?
9 It is now a sourced based prescription. It is not a
10 dose based prescription.

11 MEMBER WILLIAMSON: No, it's -- at the
12 moment, Part 35 is a dose based prescription for at
13 least the wrong site and as I understand, it's an
14 option for the target volume under the current rule
15 that's law of the land now. So if we make this
16 recommendation to OGC to reinterpret when the
17 physician can make a revision, it conflicts with the
18 way the rule is written now, so you know, my point is,
19 is that the whole medical event has to be rewritten as
20 a package for this to make sense and that's what we
21 were trying to do.

22 We went with source activity and kind of
23 geometry as the criterion for wrong site and wrongful
24 treatment of the target volume, because -- in part
25 because it was consistent with clinical -- how could

1 I say it -- workability of a very restrictive limit on
2 the ability to rewrite the written directive whereas
3 now, you know, the reason OGC ruled as it does is
4 because the misadministration -- I mean, medical even
5 determination is based on something that happens 30
6 days later and so you'd have to wait for it to come
7 and for the physician to see it to be able to you
8 know, meaningfully revise the absorbed dose
9 prescription for example, so what we tried to do, we
10 recognized, I thought, at that outset, this was my
11 belief, anyway, maybe I'm -- we embarked on a mistaken
12 premise, that we were stuck in a situation where there
13 had to be a rule revision anyway and so we attempted
14 to craft a consistent package that defined written
15 directive, the ability to make revisions, the
16 criterion for accuracy to the target volume, the
17 criterion for wrong siting that would all be a
18 consistent whole and would be more workable and
19 decidable than the current package.

20 So I think to take one fragment and push
21 it forward and say we don't need to change the rest,
22 I think would be a mistake at this point.

23 CHAIRMAN MALMUD: Thank you. Dr. Nag,
24 anything you want to add?

25 MEMBER NAG: I think, I think Dr.

1 Williamson is mistaken because we are not sending
2 those prescriptions -- the written directive to a
3 source strength based prescription. Now if we define
4 the end of the procedure as the time when you left the
5 operating room, you should still be okay. You do not
6 need one more day after that to write the
7 prescription.

8 CHAIRMAN MALMUD: You are correct, Dr.
9 Nag. The one concern that apparently Dr. Williamson
10 has is that the new definition has not yet been
11 accepted and therefore, the absence of the acceptance
12 of the new definition, the corollary to the secondary
13 issue would be applied without the new definition
14 having been entered and could create some confusion so
15 Dr. Williamson is arguing on behalf of -- since there
16 will be a change anyway, of making the change to
17 incorporate each of the issues that you have raised
18 plus his concern. Did I understand that correctly,
19 Dr. Williamson?

20 MEMBER WILLIAMSON: That's a very good
21 summary.

22 CHAIRMAN MALMUD: And Mr. Lieto has
23 already recommended that we revisit the issue after
24 the committee meeting. Would you be agreeable to
25 including that issue within the issue to be revisited

1 in --

2 MEMBER LIETO: That was the issue I was
3 addressing.

4 CHAIRMAN MALMUD: Okay, so that there is
5 agreement.

6 MEMBER LIETO: And which I think is that
7 the timing of the end of this where the written
8 directive is completed is when the surgical procedure
9 is ended. I don't see the problem.

10 MEMBER WILLIAMSON: I certainly am not
11 disagreeing.

12 MEMBER LIETO: Whether the definition is
13 dose based or strength based is immaterial to when
14 that occurs.

15 CHAIRMAN MALMUD: You believe that the
16 issue is independent of whether it's dose -- whether
17 the written directive is dose --

18 MEMBER LIETO: As to when the written
19 directive is completed.

20 CHAIRMAN MALMUD: Do you agree with that,
21 Dr. Williamson?

22 MEMBER WILLIAMSON: I don't know. I would
23 ask Mr. Lieto to clarify what he means. Does he mean
24 that we should make this as a recommendation right now
25 as an interpretation of the current Part 35 or does he

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1 mean that should be included in our proposed package
2 of rulemaking?

3 MEMBER LIETO: That it would be included
4 in our proposed package coming back to the --

5 MEMBER WILLIAMSON: Oh, I fully accept
6 that. I think the committee -- the subcommittee is on
7 record as having supported that interpretation in the
8 new rule package that we are attempting to craft and
9 I fully support that.

10 CHAIRMAN MALMUD: And therefore, Dr.
11 Zelac's concern will be dealt with as part of the
12 package that you're going to put together.

13 MEMBER WILLIAMSON: That was the intent.

14 CHAIRMAN MALMUD: Dr. Zelac?

15 DR. ZELAC: We should probably conclude
16 this portion of the discussion by noting that if the
17 subcommittee's intent to go to an activity based
18 provision of information in the written directive is
19 accepted by the entire committee and moves forward,
20 this will probably be one of the little bites that
21 Commissioner McGaffigan was discussing yesterday in
22 that there's a specific area on medical events which,
23 as written currently, is not adequately doing its job
24 and that there is an easy fix, straightforward that
25 could be incorporated into a slightly revised Part 35.

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1 CHAIRMAN MALMUD: So with that closure, it
2 appears that the task before us is clear and that the
3 subcommittee will be able to create a quote "little
4 bite", end quote, that hopefully will be acceptable
5 and deal with each of these issues and also prevent
6 the kind of occurrence that was cited earlier as an
7 example of what we see as sub-optimal practice.

8 May we move, therefore, onto the -- is
9 there anything else that you want to cover it his
10 discussion?

11 MEMBER WILLIAMSON: The third point, okay.
12 Let's see, where's our summary? Okay, so we have
13 covered the completion of written directive. Can you
14 remind me, Dr. Diamond, what's the third point?

15 MEMBER DIAMOND: It has to do with the
16 quality of -- quality control, not necessarily a --

17 MEMBER WILLIAMSON: Yeah, that's right, an
18 issue that has not really been covered is I guess what
19 the Commission charged us using the wording of more
20 effectively communicating the risks associated with
21 the medical event. So there were a number of
22 recommendations made. Let me try to find -- here we
23 are. I'm looking at Dr. Nag's, okay. I'm going to
24 expand this so you can see it a little better.

25 CHAIRMAN MALMUD: Thank you.

1 MEMBER WILLIAMSON: Is that okay?

2 CHAIRMAN MALMUD: Yes.

3 MEMBER WILLIAMSON: Okay, there were
4 really two things associated with this but you know,
5 the main thing that was supported was a concept that
6 the 35.3045 ME reporting rule as a technical
7 performance indicator should be decoupled from its use
8 as a potential patient harm index. There were a lot
9 of reasons for that. Among the rationales is, is that
10 any attempt to create a threshold that would be
11 significant with respect to patient injury or tumor
12 recurrence due to under-dose, would be site and maybe
13 even patient specific in that you couldn't come up and
14 say you know, one percentage, 20 percent covers all
15 comers, so it seemed to us and in the keeping with a
16 performance based system, what you need is something
17 as an end point that every practitioner would regard
18 as being a reasonable harbinger. If you violated it,
19 that you have some potential QA problems in your
20 organization that needed to be followed up on. So at
21 least with this perspective in mind, we recommended
22 that.

23 So one of the specifics was, is to this
24 end, the patient reporting requirement, 35.2045(e)
25 should be amended to require informing the patient

1 and/or friends and relatives only if the licensee
2 determines that the medical event might have harmed
3 the patient, could potentially harm the patient, or is
4 materially relevant to the patient's future medical
5 treatment decisions. And that otherwise, it should be
6 left as, you know, part of the practice of medicine
7 for the physician to decide the terms on which this is
8 discussed, you know, with the patient and referring
9 physicians and relatives and so forth, you know, based
10 on, you know, the practice standards.

11 So this was the one specific thing we came
12 up with was very early on in our deliberations, and I
13 don't know whether the subcommittee, you know, still
14 supports it.

15 CHAIRMAN MALMUD: Discussion of this item.

16 MEMBER NAG: Actually this is one place
17 where the entire subcommittee felt nothing but
18 unanimous. We all agreed and we felt this should go
19 forward. And when I discussed it with all the other
20 practicing people, they felt that this all would be
21 agreeable.

22 CHAIRMAN MALMUD: Dr. Diamond?

23 MEMBER DIAMOND: I strongly also support
24 this concept. We were trying to encourage the
25 authorized users to submit and to report these ME's.

1 If it is felt that it is punitive, it will trigger an
2 automatic hammer blow, then it will not serve its
3 purpose. It will be regulation that will have no
4 value and Commissioner Merrifield said it three times
5 yesterday,

6 "We have reporting requirements and, therefore, we
7 have an obligation to make sure that the reporting is
8 concise, easy to understand and is not necessarily
9 punitive".

10 The other corollary is that it is
11 important that this language be included because in
12 our increasingly medically litigious environment,
13 particularly in my home state, the great state of
14 Florida, this is a real issue. And, in fact, in the
15 wisdom of the people in the great state of Florida in
16 November, they passed a constitutional amendment, I
17 think it's number 8, in which quality control
18 deliberations may now no longer be protected as
19 privileged information. And it's a disaster what's
20 going on right now. So I think that just having this
21 type of language in here, yields some context which is
22 very helpful.

23 CHAIRMAN MALMUD: May I ask a question as
24 a naive consumer in this situation rather than as a
25 member of the committee? The term "could potentially

1 harm the patient", technically all radiation could
2 potentially harm the patient.

3 MEMBER DIAMOND: Yes, I was very careful
4 to say I support the concept. I'm not sure if this
5 precise language is what we want because again,
6 there's no way at the conclusion of an implant that we
7 can know for certainty whether a harm will occur in
8 the weeks, months or years into the future, yet on the
9 flip side, using the conditional tense of could, well,
10 that may render it meaningless as well.

11 CHAIRMAN MALMUD: Agreed.

12 MEMBER DIAMOND: So I support the concept.
13 The word smithing will need to be worked out.

14 CHAIRMAN MALMUD: Okay, Dr. Suleiman.

15 MEMBER SULEIMAN: The paragraph bothers
16 me.

17 MEMBER DIAMOND: The second sentence
18 bothers me.

19 MEMBER SULEIMAN: Because if you've gone
20 to the trouble of defining a medical event, which is
21 over and above normal medical practice, what you're
22 saying there is you may or you may not report it. So
23 --

24 MEMBER NAG: No, no, I'm telling --

25 MEMBER SULEIMAN: That's how I read it.

1 MEMBER NAG: No. You are supposed to
2 report it, but that reporting is not to be taken as an
3 enforcement issue. It's taken as a quality indicator,
4 not as an enforcement issue.

5 MEMBER SULEIMAN: But isn't that a medical
6 decision anyway? I mean, during -- if it's within
7 your -- I mean, if you're undergoing therapy, you're
8 dealing with serious consequences as Dr. Malmud had
9 mentioned yesterday. So that's just part of the
10 normal treatment.

11 MEMBER DIAMOND: Let me give an example.
12 We -- as you know, the largest number of medical
13 events in the last several years were related to
14 vascular brachytherapy. Many of these were incidents
15 of absolutely no medical consequence. A person is
16 using a vascular brachytherapy device and for whatever
17 reason, there's a kink and for a total of 30 seconds
18 the common iliac artery is radiated. There's
19 absolutely no medical effect with any reason that
20 could occur from that. In the current definition,
21 that medical event would have to be reported to the
22 patient and referring physician and so forth, and that
23 only -- that serves no purpose. It can only be
24 detrimental in many ways, so that's the purpose of
25 this sentence.

1 MEMBER SULEIMAN: But that doesn't strike
2 me as a high level of risk over and above the inherent
3 risk of the procedure in the first place.

4 MEMBER DIAMOND: I concur.

5 MEMBER WILLIAMSON: I think just for
6 clarification, the word "report" here means not report
7 to NRC.

8 MEMBER DIAMOND: To the patient.

9 MEMBER WILLIAMSON: Any event that is a
10 medical event under the criteria, all 100 percent of
11 them, would be reported to NRC. That is not the
12 issue. This is report of further --

13 MEMBER DIAMOND: Patient reporting.

14 MEMBER WILLIAMSON: -- patient reporting,
15 yeah.

16 MEMBER DIAMOND: Patient reporting.

17 MEMBER WILLIAMSON: The intent here is
18 that only a subset of medical events would be reported
19 to patients.

20 CHAIRMAN MALMUD: Are there any other
21 comments regarding this? Al?

22 MEMBER RAIZNER: This is something that
23 happens every day. We tell patients about things that
24 vary during a procedure that isn't necessarily a
25 warning to them that something terrible has gone on.

1 And I'm not sure I see a problem with telling a
2 patient that I reported a medical event but the
3 medical event was -- you know, that we had to implant
4 more seeds. We don't think there's any problem with
5 that but informing them that we've done that. I don't
6 think that's either punitive for the physician nor a
7 warning sign to the patient. It's just explaining
8 what you did during your procedure. I don't think
9 this deviates from what we do every day.

10 MEMBER NAG: May I?

11 CHAIRMAN MALMUD: Dr. Nag.

12 MEMBER NAG: Apparently the word "medical
13 event" means that you have to inform the patient in
14 writing. Many times the patient may have gone home
15 and you will scare them by saying, "Oh, we had a
16 medical event where you had X percent less or X
17 percent more". Certainly, when you report that to the
18 NRC, apparently any medical event, although it is
19 taken as if -- not always, as if you are going to have
20 a punitive action or some enforcement. And what we
21 are saying is that this medical event reporting should
22 not -- it should not be a -- there should not be a
23 need here to an enforcement and punitive action and it
24 should not require you to -- It's unlikely the patient
25 would be reporting a medical event unless that medical

1 event was to such an extent that -- you know, that
2 there would be a potential problem, and I think the
3 commissioners were talking about abnormal occurrences
4 and medical event and maybe this would be such that
5 the abnormal occurrences are reported to the patient
6 but not a medical event.

7 CHAIRMAN MALMUD: Al?

8 MEMBER RAIZNER: The problem that I see
9 with the wording here is that it relies on just the
10 licensee's perception that something has caused harm
11 and since we're changing this to source and the
12 written directive to be completed so we know whether
13 there's a deviation or not immediately following the
14 procedure, this is something that could be explained
15 to the patient immediately afterwards but in the
16 example given where 15 percent of the source wound up
17 in the bladder, the licensee may say, "Well, I don't
18 think any harm is going to come of that. The patient
19 discovers six months later that this was reported to
20 the NRC and says, "Well, there's the problem, that
21 they never told me about something", and quite a bit
22 of difference in -- I mean, there's a lot of leeway
23 given to the licensee that I don't know that we
24 should.

25 CHAIRMAN MALMUD: Dr. Zelac?

1 DR. ZELAC: Although certain licensees
2 have the perception that reporting a medical event is
3 intended to or will result in punitive action, that
4 has never been the case since the rule was first put
5 into place. Medical event is for gathering of
6 information. The intent is to use it as a quality
7 assurance tool to see when practice is outside of the
8 bounds of what would be considered as reasonably
9 acceptable in the profession. And again, this relates
10 to radiation safety aspects and not the practice of
11 medicine aspects.

12 The reporting to the patient of the
13 medical event was, as has been expressed, an intent to
14 keep the patient informed of what has occurred, not to
15 imply to the patient that there is harm that will
16 result but simply the fact that, "This has occurred,
17 this has been reported to an agency and we wanted you
18 to know about it".

19 CHAIRMAN MALMUD: Thank you. Dr. Eggli?

20 MEMBER EGGLI: As a Nebraska farm boy who
21 likes to simplify things, it strikes me that the core
22 problem here is that the definition of medical event
23 overlaps the standards of acceptable practice and the
24 whole problem seems to evolve from that reality. So
25 what we -- I think that -- I don't know that you need

1 to change the reporting mechanism for medical event.
2 I think what you have to make is a medical event, not
3 overlap the spectrum of acceptable practice. And I
4 think that's the core problem here.

5 CHAIRMAN MALMUD: Thank you. I think Mr.
6 Lieto was next.

7 MEMBER LIETO: I just want to point out to
8 people a couple of things. When you report a medical
9 event, that has to be done within 24 hours of
10 discovery. It goes into a national -- it's the same
11 reporting as the nuclear power reactor's report any
12 event associated with them. It goes into the same
13 center and is reported within a matter of probably a
14 day, goes onto the NRC website as an event. And that
15 was part of the issue that I had on the subcommittee
16 with decoupling this reporting mechanism.

17 It wasn't just with the patient, it's just
18 the whole mechanism on how reporting events, just as
19 Dr. Eggli points out, that may actually overlap the
20 practice within an acceptable range, has the same
21 connotation of an event, okay, as something that
22 occurs abnormally at a nuclear power plant. Okay, and
23 the persons that are taking this report are simply
24 there as individuals to take a report. There's not
25 any -- you know, basically just data gathers in a

1 sense.

2 Now, the fact that this does trigger
3 within a matter of days an onsite investigation team
4 or follow-up team to your facility is -- I'll accept
5 Dr. Zelac's comment that it's not meant to be
6 punitive, but as -- I think if you ask any licensee if
7 you have two or three NRC inspectors from inspection
8 or enforcement showing up at your doorstep,
9 investigating something, everything is open, okay.
10 Everything is up for, you know, grabs there, so you
11 may think that it's not punitive and maybe their
12 intent is not to, but I would probably guess that 100
13 percent of licensees would sure as heck look at it as
14 being that way.

15 CHAIRMAN MALMUD: It think Dr. Williamson
16 is next, then Dr. Nag.

17 MEMBER WILLIAMSON: Well, certainly there
18 is no intent of this statement to discourage
19 physicians from discussing and reporting this to
20 patients and I think Dr. Raizner raises a good point
21 that this -- eventually the medical events and their
22 current handling become public information. It would
23 be extremely imprudent for physicians not to discuss
24 it with their patients. But the idea is to I think
25 give the patients and physicians some control over the

1 forum and format and presentation of this because you
2 know, currently you get this lengthy report and it's
3 kind of -- the physician loses control over the venue
4 and method by which this is presented and in some
5 situations, we had one at Washington University, that
6 you know, consumed tens of thousands of dollars of
7 staff time.

8 It was heavily litigated. I just can't
9 tell you how many hours it took and, you know, it
10 involved a situation where a physician explicitly made
11 the judgment that it was not medically appropriate to
12 report it in the way NRC wanted to the patient because
13 of the tenuous -- the problem of basically patient
14 compliance with the treatment and mental status of the
15 patient. But yet, the patient did not have a legal
16 guardian and so the NRC regulations basically forced
17 Washington University to pick out, you know,
18 essentially a relative or friend that had no legal
19 standing in these matters. So that was a problem for
20 the institution. So it's, I think, an issue of
21 control.

22 CHAIRMAN MALMUD: I think that you did
23 make a valuable point and that is that it's the
24 medical event that's going to be reported. It's doing
25 to be on a website and therefore, open to the public.

1 It would be a very unwise physician who did not
2 discuss the fact that this event had occurred with the
3 patient, with the risk of the patient learning about
4 it from a stranger who happened to see the patient's
5 name or incident. Is the name actually --

6 MEMBER LIETO: No, no.

7 CHAIRMAN MALMUD: All right, so the
8 patient was not necessarily discovered in that manner.
9 But it's a wise physician who would not allow a
10 patient to learn something about himself or herself
11 from an external source rather than from the
12 physician. However, that's a physician decision. We
13 get back to the point here, was there a consensus
14 amount the committee that this should move forward?
15 Was there any dissent? Therefore, if the subcommittee
16 wishes it to move forward, shall the whole committee
17 accept this as a motion?

18 PARTICIPANT: To move forward?

19 CHAIRMAN MALMUD: Yes. Is there a second
20 to the motion?

21 MEMBER NAG: Yes.

22 CHAIRMAN MALMUD: Okay, so the motion has
23 been moved and seconded. Is there any further
24 discussion on the part of the entire ACMUI committee
25 regarding this? If not, all in favor? Any opposed?

1 Any abstentions? It carries unanimously as a motion
2 of the ACMUI. Thank you.

3 Next item.

4 MEMBER WILLIAMSON: All right, let's see
5 what we have here that's potentially votable on. I
6 think this is a reasonable provision for us to look
7 at, Number C, "As long as any event reporting is not
8 automatically treated as an indicator of potential
9 patient harm, the subcommittee agrees with Dr.
10 Siegel's assessment that 20 percent is a reasonable
11 action level for reporting events of QA significance
12 to NRC for temporary implants, external beam
13 treatments and unsealed radiopharmaceutical
14 administrations".

15 That was basically, you know, our
16 statement -- the statement of the subcommittee on the
17 wisdom or lack therein, of the 20 percent threshold,
18 which as you recall was one of our specific charges.

19 CHAIRMAN MALMUD: Dr. Nag?

20 MEMBER NAG: Actually, this is
21 supportable. In fact, you can make it more universal
22 because even permanent implant would be included if it
23 is not dose-based because if it is 20 percent and it
24 is source strength based that is also included in the
25 20 percent.

1 CHAIRMAN MALMUD: Dr. Eggli?

2 MEMBER EGGLI: I'm sorry, Mr. Chairman,
3 I'm still missing this. If normal practice overlaps
4 this range, why are we setting this threshold? If
5 normal practice only effects a subset of this, maybe
6 that piece should be pulled out but it strikes me
7 again that the whole problem revolves around the
8 acceptable practice overlapping the definition of
9 medical event. How can it be a medical event if it is
10 acceptable practice? Again, somebody please help me
11 understand that.

12 CHAIRMAN MALMUD: Dr. Suleiman, are you
13 going to try to --

14 MEMBER SULEIMAN: No, I'm going to concur
15 with exactly what you're saying. I think the
16 uncertainty and the dose prescription is such that
17 it's -- in some cases it's going to be greater than 20
18 percent so arbitrarily assigning 20 percent across the
19 board for especially unsealed radiopharmaceuticals, is
20 disturbing to me as well. I know there's an effort to
21 come up with a nice numerical metric but the practice
22 of medicine clearly in some cases is going to exceed
23 that and maybe in some cases 20 percent is too much,
24 but I think to try to address it in a broad spectrum
25 like that is going to cause a lot of anxiety.

1 CHAIRMAN MALMUD: Dr. Diamond?

2 MEMBER DIAMOND: This is also a very
3 difficult issue the more you think about it and this
4 is what Dr. -- what Commissioner Merrifield again said
5 yesterday. What data do you have to support that 20
6 percent is a meaningful number. What data do you have
7 to support that 21 percent is going to cause a harm
8 and therefore, is worthy of this consideration? And
9 the point is, is that that's not a question that is
10 answerable.

11 In many cases, 30, 40, 50, 80 percent may
12 have no bearing whatsoever. There are some potential
13 other cases where less than 20 percent may be of
14 concern. So I don't know how to answer that question
15 but it is -- the more one things about it, the more
16 difficult it becomes.

17 MEMBER EGGLI: If I could sort of respond,
18 it strikes me just as a common sense point of view
19 that a medical event has to fall outside the range of
20 acceptable practice.

21 CHAIRMAN MALMUD: Dr. Williamson.

22 MEMBER WILLIAMSON: Well, I think there's
23 -- two objections have been raised, I think. Dr.
24 Diamond has raised the objection that, you know,
25 there's no assurance this is correlated with patient

1 harm. I just wish to remind the group that the
2 premise, the hypothesis of this statement is that it's
3 unrelated and has no relation to patient harm. It is
4 a performance indicator that NRC can, you know, use at
5 its discretion to determine whether further action
6 against that licensee is needed or the system needs to
7 be tinkered with or whatever.

8 It's an indicator that drives their
9 performance based rule system. So they have to have
10 something.

11 MEMBER EGGLI: You know, again, Jeff, I'm
12 sorry to re-emphasize this, how can -- if it overlaps
13 normal practice, how can it be a performance
14 indicator?

15 MEMBER WILLIAMSON: Well, that's the
16 second -- and you raised, Dr. Eggli, a very good
17 question. I think you know, we have not really
18 considered radiopharmaceuticals in our deliberations
19 in any detail. We did think about temporary
20 brachytherapy at some length, we thought about
21 external beam, those are both scenarios in which the
22 practitioner has a lot of control over the total
23 treatment time and ability while the treatment is in
24 process to make revisions or stop or do corrective
25 action. So we felt that 20 percent was reasonable

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1 criterion and did not overlap basically the normal
2 variations of clinical practice, given the way
3 brachytherapy and external beam are done.

4 MEMBER EGGLI: But I swear that's not what
5 I heard here. I've heard that are lots of occasions
6 where in fact, the range of normal may overlap 20
7 percent in permanent brachytherapy.

8 MEMBER DIAMOND: What's your solution,
9 Doug?

10 MEMBER EGGLI: Unfortunately, I don't have
11 a great solution. I think that range of normal has to
12 be -- range of normal practice has to be outside of
13 the normal occurrence rate and if that can't be
14 defined with a dose limit, then we're going to have to
15 go to --

16 MEMBER WILLIAMSON: May I --

17 MEMBER DIAMOND: We have to do something,
18 though.

19 CHAIRMAN MALMUD: Wait. We need to have
20 one speaker at a time.

21 MEMBER EGGLI: Then we have to go to a
22 performance based indicator that's not coupled to some
23 kind of a number.

24 MEMBER WILLIAMSON: May I point out that
25 specifically excluded from this statement is permanent

1 brachytherapy. Read it, it does not say permanent
2 brachytherapy in there. That is the one in fact, that
3 we have singled out for all this attention. So, you
4 know, I think we all would concede we have not had as
5 much expertise and we have not thought through
6 radiopharmaceuticals and perhaps it would be prudent
7 to delete that from the list.

8 MEMBER EGGLI: Unfortunately
9 radiopharmaceuticals are specified based on dose
10 administered.

11 MEMBER WILLIAMSON: Yes.

12 MEMBER EGGLI: And that's a very
13 measurable quantity that is appropriate and should
14 fall within the range specified, so we don't specify
15 a distribution. We don't specify a target volume. We
16 don't specify a radiation to a target organ. We
17 simply specify dose to be administered. So that can
18 be very carefully measured and very tightly
19 controlled. I don't think we're going to have any
20 radiopharmaceutical problems.

21 MEMBER WILLIAMSON: Well, we felt that the
22 analogy, you know, in external beam and in temporary
23 brachytherapy was somewhat similar, that effectively
24 it can be specified fairly precisely. Where there are
25 deviations, the nature of the procedure with the

1 ability to make revisions and/or corrections before
2 the end of treatment, there is enough latitude to
3 easily be able to make this and this is, you know,
4 several times over the normal limit in our departments
5 that we would use as a threshold for instituting
6 investigations and our own corrective actions as part
7 of our comprehensive QA program. So we thought it
8 was, you know, a reasonable guideline.

9 CHAIRMAN MALMUD: Isn't the current action
10 level 20 percent?

11 MEMBER NAG: Yes.

12 CHAIRMAN MALMUD: So why is this statement
13 necessary at all.

14 MEMBER WILLIAMSON: Because we were asked
15 as a charge of our subcommittee to make a
16 determination if the 20 percent threshold is
17 reasonable.

18 CHAIRMAN MALMUD: So the committee is
19 reaffirming --

20 MEMBER LIETO: For all modalities.

21 CHAIRMAN MALMUD: For all modalities?

22 MEMBER WILLIAMSON: Except permanent
23 brachytherapy.

24 CHAIRMAN MALMUD: It doesn't say except
25 permanent brachytherapy.

1 MEMBER LIETO: I'm sorry, Mr. Chairman,
2 the charge asked us to look at the -- all modalities
3 in terms of plus or minus 20 percent. And what we're
4 saying is that we reaffirmed it for all modalities
5 except permanent implants. So we're just reaffirming
6 that the 20 percent as a quality assurance indicator
7 is appropriate for those modalities except permanent
8 implants as opposed to coming up with a different
9 evaluation and so forth for radiopharmaceutical
10 therapies, temporary implants and so forth.

11 MEMBER WILLIAMSON: And again, notice, you
12 know, as long as ME event is not automatically treated
13 as an indicator of potential patient harm, that was an
14 important clause of this and it's enumerated there
15 what modalities we think this is appropriate for.

16 CHAIRMAN MALMUD: Okay, Dr. Suleiman?

17 MEMBER SULEIMAN: Yeah, I think a point
18 for clarification to keep my thinking straight, you
19 may have two facilities that may prescribe a
20 difference in administered dose by 30 percent.
21 They've reached their own decisions. That's practice
22 of medicine deviation. But in fact, when they go to
23 administer X amount of dose, they've exceeded it by 20
24 percent. That's a reportable medical even, even
25 though Facility B may be giving 30 percent more than

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1 what the other one was.

2 CHAIRMAN MALMUD: You are correct.

3 MEMBER WILLIAMSON: Correct.

4 CHAIRMAN MALMUD: May I make a suggestion,
5 therefore, Number 1 that we delete a reference to an
6 individual in a motion. Dr. Siegel, is this Jeffrey
7 or Barry Siegel?

8 MEMBER WILLIAMSON: Barry.

9 CHAIRMAN MALMUD: All right, I'd just
10 delete the reference to the individual and just may I
11 read this? "The -- as long as a medical event -- as
12 long as medical event reporting is" --

13 MEMBER WILLIAMSON: Sorry, I was just
14 going to cross it out here. I'll do that later.

15 CHAIRMAN MALMUD: "As long as medical
16 event reporting is not automatically treated as an
17 indicator of potential patient harm, the SC agrees
18 that 20 percent remains a reasonable action level for
19 reporting events of QA significance to NRC for the
20 following modalities: temporary implants, external
21 beam treatments and unsealed radiopharmaceutical
22 administrations." Is that wording acceptable to the
23 subcommittee?

24 Will the subcommittee accept that as a
25 motion of the subcommittee? Is there a second to the

1 motion? Any discussion? All in favor? Any opposed?
2 Any abstentions? Motion carries and it's lunch time.
3 Thank you all.

4 (Whereupon at 12:06 p.m. a luncheon recess
5 was taken.)

6 MR. ESSIG: I realize that Dr. Malmud, the
7 chairman, has not returned yet, but I'll use my
8 prerogative as Designated Federal Official to call us
9 to order so that we can stay reasonably on schedule.

10 This afternoon, we have starting with a
11 presentation from Douglas Kondziolka, if I got that
12 correctly. Close enough? From the University of
13 Pittsburgh and I think your slides are loaded on the
14 computer. You'll have to go to a microphone so that
15 the court reporter can pick you up.

16 So if you would please, begin. I'm sorry,
17 I should have said Dr. Kondziolka, I'm sorry.

18 DR. KONDZIOLKA: Thank you, Mr. Essig, and
19 ladies and gentlemen. It's a pleasure to be asked to
20 speak to you today and thank you for dimming the
21 lights.

22 We want to speak on the topic of gamma
23 knife radiosurgery and specifically the roles of
24 different physicians in this procedure.

25 I work at the University of Pittsburgh.

1 I'm a neurosurgeon with an interest in radiation. I
2 have a master's degree in neuroscience with a thesis
3 in radiation biology. Ninety-five percent of my
4 practice involves radiation administrations of some
5 kind. Most of these are related to the gamma knife.
6 Others are related to P32 isotopes for brain tumors
7 and other types of related procedures.

8 In our Center, we have a number of
9 individuals, the names at the top in white are
10 neurosurgeons, the names in green or yellow are
11 radiation oncologists. And we work together as a
12 team, a team that has been very successful at
13 promoting the use of this for our patients, both in
14 the United States and worldwide.

15 I'm a professor of neurological surgery.
16 I'm also a professor in radiation oncology. I'm
17 currently the president of the International
18 Stereotactic Radiosurgery Society. This is an
19 international member service organization where the
20 members are neurosurgeons, radiation oncologists and
21 physicists and as president of that organization, I am
22 elected to respond to the needs of all of those. And
23 I'm also past president of the American Society for
24 Stereotactic and Functional Neurosurgery.

25 David Larson who will speak after me is a

1 past president of the International Stereotactic
2 Radiosurgery Society, an organization that seems to
3 alternate who the presidents are. I don't see David
4 here yet, but he is a taller, much better looking man
5 than I am and I will spend his time trying to speak
6 against some of the concepts that I'm going to bring
7 to you today.

8 In fact, what he is going to speak and he
9 and I have talked on the phone a few weeks ago about
10 what we're each going to speak about, we're both good
11 friends. He is going to talk to you about keeping the
12 status quo and I'm going to talk to you about
13 improving the status quo.

14 Specifically, my experience in gamma knife
15 radiosurgery includes over 3,000 personal cases. We
16 performed our seven thousandth institutional case last
17 month. There have been over a thousand animal
18 experiments, probably more than anybody in the world.
19 I've written over 200 peer-reviewed journal
20 publications, 100 book chapters, edited three books
21 and am the current editor of the journal called
22 Radiosurgery.

23 I'm also director of a course entitled
24 "Principles and Practice of Gamma Knife Radiosurgery"
25 which the vast majority of people who use this

1 technology in the United States take this one-week
2 immersion course. We run now 45 courses and these are
3 the number of people that I have personally trained,
4 including 286 neurosurgeons and 233 radiation
5 oncologists and 86 medical physicists.

6 The gamma knife is one of a number of
7 expensive medical technologies that we have at our
8 disposal and many of these are familiar to you,
9 including CT scans, MRI scans and other radiosurgery
10 devices such as this cyber knife device here. And we
11 have three gamma knife units. Interestingly, we
12 manage all of these gamma knife units as operating
13 rooms and they're under the operating room schedule
14 and staffed by operating room personnel.

15 Here's what they look like. The first
16 unit installed in the United States, 1987. The second
17 unit put in in 1996 and a third unit upgraded earlier
18 this year.

19 I'm going to argue to you that in favor of
20 the radiosurgery team and that no individual is more
21 important than any other individual and that they each
22 bring strengths related to efficacy and safety to this
23 procedure. Interestingly, in other countries, most
24 other countries in the world, this team approach is
25 not used. In fact, in most other countries the team

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1 includes the neurosurgeon and that's it. Most other
2 countries do not have a radiation oncologist as part
3 of this procedure. And few, in fact, have a medical
4 physicist. We do not support this. We support the
5 team approach as it is listed here.

6 So what is this? This is a single session
7 of radiation through the skull, using image-guidance
8 to define specific brain target. That target, as I'm
9 going to show you, can be a disease. It can also be
10 normal brain to treat a specific problem and there are
11 various ways to do this in the United States. The
12 gamma knife that we're talking about which is under
13 the purview of the Nuclear Regulatory Commission,
14 linear accelerators or charged particle facilities.

15 This is a multi-disciplinary procedure and
16 what I'm going to say is that no neurosurgeon should
17 do this procedure without a trained radiation
18 oncologist, not any radiation oncologist, a trained
19 radiation oncologist. And a radiation oncologist to
20 work with a trained neurosurgeon, not any
21 neurosurgeon.

22 Any other concept working with anybody,
23 any radiation oncologist just because they completed
24 radiation oncology residency does not empower them nor
25 give them a real understanding of how to do this

1 procedure and is not in the best interest of the
2 public. We are going to make an argument that we
3 wanted trained mentored, quality people doing this
4 procedure.

5 So what's the problem? Well, the problem
6 is that unfortunately NRC regulations do not require
7 neurosurgeons as authorized users of the procedure.
8 In fact, when hospitals were the only sites putting in
9 gamma knife units, this was not really a big deal
10 because locally the hospital credentialing committees
11 and so on mandated who would have to be there.

12 However, there are now facilities putting
13 in these devices outside of hospitals, free-standing
14 facilities. In fact, almost 10 percent of gamma knife
15 units in the United States are now not even owned by
16 medical centers and can be privately owned by a
17 radiation oncology group or a neurosurgical group and
18 therefore the NRC rules are being used incorrectly or
19 may not even apply.

20 So for example, in eastern Pennsylvania,
21 radiation oncologists use the NRC regulations to keep
22 a neurosurgeon out of the procedure. Later on, we'll
23 show you what this could mean.

24 Now we don't really think this is what the
25 NRC meant with its current regulations that mandate

1 that the authorized users be a radiation oncologist
2 and a medical physicist. Who suffers from this?
3 Well, the patient obviously is the one in jeopardy.

4 Let's show you this procedure. This
5 procedure starts at our facility early in the morning.
6 We have a patient. We have a neurosurgeon applying
7 the stereotactic frame, the stereotactic imaging to
8 define the brain target is then supervised by the
9 neurosurgeon. At our facility, the physicist brings
10 in the images and then the neurosurgeon does the dose
11 planning and then checks the dose planning with the
12 radiation oncologist and then jointly they select the
13 dose. The neurosurgeon sets the patient up in the
14 gamma knife machine. The radiation oncologist also
15 could do this and sometimes it's done together.
16 Usually, the neurosurgeon, together with the radiation
17 oncologist, then provides the administration and
18 monitors the patient.

19 It's important to remember that this is,
20 in fact, my patient as a neurosurgeon and I don't want
21 anybody else monitoring the patient from the
22 standpoint of their general medical care, not just the
23 radiation care.

24 In fact, you look at all elements of this
25 procedure and I've divided these into about 10 or 11

1 different elements from start to finish. Patient
2 selection, which is done jointly. However, once we
3 start with the patient's procedure, sedating them,
4 putting the frame on, the imaging, this is a
5 neurosurgical workload. Setting up the dose plan,
6 planning it, the selection. This is done jointly.
7 The patient setup, dose delivery, then jointly. The
8 general medical issues are handled by the
9 neurosurgeon, the frame removal by the neurosurgeon
10 and the post-op care by the neurosurgeon.

11 And so if one was to actually look at all
12 the different elements of the procedure, there's only
13 person who really can do everything. But the NRC does
14 not recognize neurosurgeons as authorized users. This
15 was not always true. In fact, I was an authorized
16 user for many years. Took a long time to become one.
17 I had to provide evidence including virtually more
18 than a thousand patients and a number of years ago I
19 quote lost this license although I was never informed
20 that I lost my license. It was just an NRC change in
21 regulation.

22 So what's the risk again. The risk is
23 safe patient radiosurgery. Now why is this at risk?
24 Well, first of all, radiation oncologists are not
25 trained in many of the components of radiosurgery.

1 They're not trained in their residency. And they're
2 not trained in their practice. And the effects of
3 this procedure can be dangerous, as in any surgical
4 procedure.

5 Now the neurosurgeon is required by
6 training to remain present during all his or her
7 procedures, any kind of operation that we do because
8 who else will take care of the medical emergencies?
9 Radiation oncologists are really not trained to do
10 that.

11 My name is on a hospital chart and it's my
12 patient that day and I carry the greatest medical
13 liability risk of anybody involved in the procedure.
14 In fact, if you go -- forget ASTRO and these
15 organizations that are member service organizations.
16 If you go to the actual boards of both Radiation
17 Oncology and Neurological Surgery which mandate
18 education, because this is what we're talking about as
19 we go forth, the definition of what neurosurgery is
20 includes stereotactic radiosurgery.

21 From the ACGME and the Residency Review
22 Committee, this is again the national educational
23 requirements in neurosurgery, the spectrum of training
24 should include craniotomies as opening the brain,
25 traditional surgeries as you consider, and

1 stereotactic surgery, including radiosurgery.
2 Training in this is mandated by the American Board of
3 Neurological Surgeries. It's not an afterthought.

4 If one goes to the radiation oncology
5 recommendations for training, including what the
6 definition of a radiation oncologist talks more
7 broadly about branches of clinical medicine that
8 radiation oncologists perform with, does not
9 specifically mention radiosurgery.

10 Under clinical training for radiation
11 oncologists, it talks mostly about facilities and what
12 should be there. It doesn't mention that you should
13 have a gamma knife, for example. But it does mention
14 that the curriculum should provide instruction in
15 radiation and cancer biology and the clinical
16 applicability to the areas and it does mention
17 radiosurgery.

18 Our training from neurosurgery residents
19 at the University of Pittsburgh includes a four-month
20 rotation for all neurosurgery trainees participating
21 in over 250 cases. I will tell you that within our
22 own Department of Radiation Oncology, there is no
23 formal training in gamma knife radiosurgery for the
24 radiation oncology residents and no Pittsburgh
25 residence see a case from start to finish. This is a

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1 testimony to how serious neurosurgery takes gamma
2 knife education as opposed to radiation oncology.

3 Now let's take another look at other
4 organizations. The JCAHO, looking at quality health
5 care and safe health care within hospitals, certifies
6 its service as surgical. Ninety percent of these
7 units are set up and staffed as neurosurgical units.
8 They pay for this under neurosurgery procedural codes
9 and Medicare and patient pays this procedure as
10 neurosurgery.

11 So let's get back to patient safety.
12 Radiation oncologists, who are wonderful people and an
13 important part of the team, however, are not specialty
14 trained in neuroanatomy. They're not specialty
15 trained in stereotactic frame user imaging. They're
16 not specialty trained in many of the disorders that
17 are treated with radiosurgery or in acute patient
18 care.

19 They're not specialty trained in brain
20 vascular malformations which were initially 50 percent
21 of the cases. These are diseases that are not seen in
22 the radiation oncology residency traditionally. That
23 number is down now to about 10 percent of the overall
24 case load. They're not trained really in the
25 management of medically refractory facial pain

1 syndromes like trigeminal neuralgia. They're
2 certainly not medically trained in movement disorders
3 such as Parkinson's Disease. And interestingly,
4 radiation oncologists are really not even trained in
5 high dose, single session of radiation.

6 So one argument that has been made as well
7 is that radiation oncologists understand radiation.
8 But when I start to talk to them in my training
9 courses about we're going to get 90 gray to the
10 trigeminal nerve, most radiation oncologists look at
11 me and say 90 gray? To a nerve? In 20 minutes?
12 We've never seen a dose like this.

13 Here's a child with a brain stem
14 arteriovenous malformation. This is an MRI scan.
15 Here's the pons, the middle of the brainstem with all
16 the nerves running down to the arms and legs. This is
17 a little tangle of blood vessels here. This is
18 critical brain with a little blood vessel
19 malformation. Here's a gamma knife radiosurgery plan
20 for that blood vessel malformation. And hopefully
21 that will cure the AVM. But this is a very risky
22 thing to do. The gamma knife approach may be the only
23 reasonable strategy for this disease. The outcomes of
24 this work have been published by neurosurgeons jointly
25 with radiation oncologists, but led by neurosurgeons.

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1 This is an essential tremor patient, an
2 81-year-old man with the shakes. I can't control his
3 hand. This is the thalamus. This is a movement
4 coordination area of the brain. This is a single shot
5 with the gamma knife targeted here using specialized
6 brain mapping techniques. This is his ability to draw
7 a circle, a spiral. You can see he can't draw a
8 spiral.

9 We're going to put 140 gray with a four
10 millimeter collimator into the thalamus. This is what
11 it looks like in four months and we hope that his
12 tremor will have gone away. The alternative to this
13 is to put an electrode in the brain, so a neurosurgeon
14 makes the decision as to do -- we put an electrode, do
15 we treat this with radiation with the gamma knife, how
16 do we select these patients, how do we even target
17 this part of the brain. In fact, many neurosurgeons
18 don't even know how to do this.

19 We have special calculation based-ways to
20 find the brain target. We aim a tremendous amount of
21 radiation there. The patient's tremor is relieved
22 after four months. It's a wonderful procedure. This
23 is not something a radiation oncologist would ever see
24 in their training. It's not something that
25 neurosurgeons see very often, but they do see it, but

1 the key is the brain anatomy in understanding that.

2 What happens if we were wrong? Say that
3 a radiation oncologist decided to treat Parkinson's
4 Disease and they were a little off in their targeting
5 because they didn't understand brain anatomy. If this
6 target was 2 millimeters to the right, the patient
7 would be paralyzed. If it was 2 millimeters back,
8 they'd be numb. Four millimeters to the inside, have
9 thinking problems. Too far forward, it wouldn't work.

10 Radiation oncologists also have limited
11 training in these tumors, acoustic neuromas, now
12 probably the commonest benign tumor we do. Skull-
13 based meningiomas, pituitary tumors. Performing
14 complex multi-technology procedures and understanding
15 the availability of the alternative choices for these
16 disorders.

17 Here is a 73-year-old woman who is a
18 neurosurgeon's mother-in-law. Now of course,
19 neurosurgeons, we're different in society because we
20 actually like our mothers-in-law, but here's a woman
21 who's got a brain tumor and here's what it looks like
22 in four years and here's what it looks at eight years
23 having nicely shrunk. The alternative was to open
24 this woman's head.

25 The outcomes published with radiosurgery

1 for acoustic neuromas, in The New England Journal of
2 Medicine, first published by neurosurgeons with a
3 radiation oncologist, but again led by neurosurgeons.

4 This is expanding out of children in a big
5 because, as you know, we don't want to deliver
6 radiation to the developing brain. We like to focus
7 it on the target and hopefully spare the developing
8 brain from radiation. So it's been more and more
9 utilized in children under general anesthetics and of
10 course, in order to direct a procedure like this,
11 under general anesthesia, only a surgeon is going to
12 do this.

13 But we keep hearing the argument, well,
14 the radiation oncologists are the ones who understand
15 radiation dose selection and delivery. This is not
16 really true. These high, single-session doses are not
17 really taught in radiation oncology training. Now
18 perhaps some day they will be, but they're certainly
19 not trained now.

20 And radiation oncologists do not deliver
21 such doses routinely. Of course, they deliver doses
22 in a fractionated way which is very different.

23 So the contrarian argument made in other
24 countries has been is the radiation oncologist really
25 necessary? We hear this all the time from Japan,

1 China, Switzerland, Norway. Are they necessary? Of
2 course, yes. Absolutely. We don't want to go the
3 route of these other countries. But a number of
4 things should be understood. There's nothing magical
5 to the radiation oncologist's presence for 25 minutes
6 while the beam is being delivered. And I'm monitoring
7 the patient or the physicist also is there. They
8 should be allowed to leave the suite for a few
9 minutes. The treatment can be stopped easily. It
10 takes about a minute for the patient to come out of
11 the machine and problems are rare.

12 The guidelines that exist are obviously to
13 address potential problems. We have had no
14 misadministrations in 7,000 patients at Pittsburgh.

15 Now what's really going on out there?
16 Twenty-seven gamma knife units, there's 93 in the
17 United States, 27 gamma knife units report to this
18 organization, the International Radiosurgery
19 Association that radiation oncologists routinely leave
20 the suite. It's in keeping with the general practice
21 of radiation oncology, where the therapists and the
22 technicians deliver the radiation, not the radiation
23 oncologist. The radiation oncologist is present in
24 the department, not physically sitting in a chair in
25 front of the monitor.

1 I want you also to understand that one
2 misadministration, treating the wrong side of the
3 patient's face, the wrong nerve, was performed, I
4 think, because of the problems that exist in the
5 current regulations. The neurosurgeon didn't have to
6 be there, so he left. It was his patient and the
7 patient had facial pain on the left side. Well, the
8 radiation oncologist was the one administering it, it
9 was not his patient. He was confused and there was
10 some communication problem and the right side was
11 treated, the wrong nerve. This is a problem.

12 The neurosurgeon really should be required
13 to sign the directive along with radiation
14 oncologists. Required. The NRC should never allow
15 radiation technicians or therapists to operate gamma
16 knife units. They have no training in this. We have
17 never trained one in 43 courses that we have done.

18 And again, does only a hospital have
19 oversight? Well, when now gamma knife units are not
20 owned by hospitals, may be owned by private groups and
21 are no longer even physically located at hospitals, we
22 need regulations that are clear from the Nuclear
23 Regulatory Commission that really understand how
24 radiosurgery is performed.

25 I also want to take a step back and tell

1 you that the science behind all of this, which
2 justifies why patients get this in the first place,
3 who are the scientific leaders of gamma knife
4 radiosurgery? They've really been neurosurgeons.

5 This is our scientific database room.
6 It's our research, clinical research suite of all the
7 patient files and 7,000 patients, 7,000 charts. Who
8 cares about the quality of this? Again, the vast
9 majority of the peer-reviewed literature has been
10 published by neurosurgical program with a neurosurgeon
11 as the lead investigator and all animal-based
12 radiobiological research in gamma knife radiosurgery
13 has been led by neurosurgeons.

14 So why should the radiation oncologists be
15 authorized users? The science is being done and led
16 by the neurosurgeons. This paper on experimental
17 radiobiology, looking at how it's done, why it's done
18 and where it's going, this is a neurosurgical paper
19 published in a neurosurgical journal.

20 This foray into epilepsy radiosurgery,
21 treating epileptic foci with radiation is guided by
22 imagine guidance came out of Marseilles, France.
23 There's not a radiation oncologist in this group. The
24 current NIH-funded American study is led by a
25 neurosurgeon at UCSF, together with radiation

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1 oncologist Dave Larson who will speak after me, who is
2 also one of the key investigators and another group of
3 centers who are studying the use of focused radiation
4 to treat this part of the brain. The alternative is
5 to remove this part of the brain. We're studying the
6 effects of radiation as an alternative to surgery.

7 Trigeminal neuralgia, again, a common
8 facial pain problem. Before 1992, not one patient had
9 this procedure done in the United States. Within five
10 years, 12,000 patients had had this done. This is
11 again not a disease thought in radiation oncology
12 training.

13 Here's again a magnified view of the
14 brainstem. I showed you that malformation in the
15 brainstem before. This is the trigeminal nerve.
16 Here's a single shot of radiation given at a certain
17 dose. The problem that occurred in California was
18 when neurosurgeon got to leave the case, the radiation
19 oncologist treated the other side.

20 Psychiatric disorders, anxiety disorders,
21 pain, from the neurosurgical literature not even a
22 radiation oncologist on the paper. These are studies
23 from Sweden, where the gamma knife was first
24 published.

25 Here's a patient of mine with obsessive-

1 compulsive disorder. Eight million people have this
2 problem in the United States. This is not part of
3 radiation oncology residency. We're putting shots in
4 the anterior limb of the internal capsule to block
5 projections to the frontal lobe. Again, this is
6 nothing too complex. This is simply an operating room
7 that needs to be run by a dedicated team.

8 In the traditional operating room, we have
9 a team of the surgeon, the anesthesiologist, the
10 nursing staff. In the gamma knife, we should have the
11 team of the neurosurgeon, the radiation oncologist,
12 the nursing staff, the medical physicist.

13 Support what you do here because the
14 future of surgery involves not only the concept of
15 open surgery, but the new biologic surgeries. When
16 I'm talking to neurosurgeons, I tell them that
17 radiosurgery is the first way to do surgery of cell
18 membranes. That's the first way to do surgery of DNA.

19 They need to understand it and they got
20 the message. This is why it's an important part of
21 education. We are redefining the standards of brain
22 tumor treatment with this device and the NRC should
23 redefine what it has considered it's gold standards,
24 excluding the neurosurgeons. We are asking for a gold
25 standard that brings people together as equal partners

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1 for safety and efficacy, because both groups bring
2 important things to the table and anybody who is
3 working without the other is fooling themselves.

4 This is a paper that myself, Dade
5 Lunsford, Jay Loeffler and Bill Friedman, all former
6 presidents or current presidents of the International
7 Stereotactic Radiosurgery Society, have written about
8 what radiosurgery is, how it should be done, what are
9 the different strengths that all of us bring to this
10 procedure.

11 Here are our recommendations. First, the
12 term the "authorized user" that the NRC has should be
13 eliminated. We're proposing that there should be new
14 terms. There should be an authorized neurosurgeon.
15 There should be a Board-certified or equivalent
16 neurosurgeon who has completed formal training in this
17 and has been mentored for a certain number of cases.

18 We are also asking that there should be an
19 authorized radiation oncologist. Again, not any
20 radiation oncologist, one who is board certified or
21 equivalent, has completed training and has been
22 mentored. I can tell you that the quality of the
23 radiation oncologists who come to us for training in
24 Pittsburgh is variable. I would say half of them are
25 excellent and half of them are weak. There should

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1 also be an authorized medical physicist who is
2 institutionally certified, completed formal training
3 and has been mentored.

4 We really need clean and concise
5 regulations for gamma knife radiosurgery that reflect
6 how this procedure was performed that are distinct
7 from cobalt teletherapy.

8 We also ask that either a neurosurgeon or
9 a radiation oncologist be present at the console
10 during dose delivery taking care of their joint
11 patient.

12 The authorized medical physicist should be
13 in the vicinity, but is not required to be at the
14 console since they are not medically trained.

15 And we believe that all of these changes
16 serve to augment patient safety.

17 Thank you very much.

18 [Unmic'd audience question.]

19 DR. KONDZIOLKA: Well, we know it wasn't
20 a neurosurgeon, so I don't know specifically who it
21 was. I don't know if it was a neurologist or a
22 radiation oncologist or a physician assistant. I
23 really have no idea.

24 MEMBER NAG: Does the hospital, when they
25 think about who can perform what procedures?

1 DR. KONDZIOLKA: Well, most hospitals do.
2 For example, I just renewed my hospital credentials
3 and I have to sign a long list of all the procedures
4 that I'm asking for permission to perform. But if the
5 procedure is not performed at a hospital, there's no
6 such credentialling process.

7 MEMBER NAG: Is there any harm done to a
8 patient if a radiation oncologist is present in the
9 procedure?

10 DR. KONDZIOLKA: Is there any harm done to
11 the patient if the radiation oncologist is present?

12 MEMBER NAG: Yes.

13 DR. KONDZIOLKA: Absolutely not. We want
14 the radiation oncologist present.

15 MEMBER NAG: Okay, now lots of surgeries
16 are performed where both radiation oncologist and the
17 surgeon are there, for example, gynecology
18 oncologists, all of them require a radiation
19 oncologist and a gynecologist oncologist, plus the
20 implant neurologist, the radiation oncologist;
21 pediatric surgery, and innumerable of them.

22 What is so different about neurosurgery
23 that it cannot be done in the same way and requires
24 that the neurosurgeon be the authorized user and all
25 the others, I mean gynecology oncologist can be the

1 authorized user, otherwise we wouldn't do it. We want
2 to be the authorized user, if not, we won't do it.

3 They are all trained in their surgical
4 subspecialty. We use or we work with them. What is
5 the difference in neurosurgery?

6 DR. KONDZIOLKA: There's absolutely no
7 difference. So what we want is that there should be
8 three authorized users in every procedure. There
9 should be the authorized neurosurgeon, the authorized
10 radiation oncologist and the authorized physicist.
11 Not two. You can go to the list and pick out choose
12 one or two of your choice. But we want the strongest
13 team. As part of that, we want the fact that
14 neurosurgeons should be acknowledged, that they should
15 be on an equal level with the radiation oncologist.

16 DR. KONDZIOLKA: And that's the same in
17 neurology, the same in ophthalmology, the same in
18 gynecology oncology.

19 DR. KONDZIOLKA: I'm glad you agree with
20 me.

21 MEMBER NAG: In those fields, they are not
22 called authorized users. They are called the surgeons
23 and we all agree that the surgeon has to be there and
24 --

25 DR. KONDZIOLKA: That's the problem. The

1 problem is you don't all agree, okay? You don't all
2 agree. In this case in eastern Pennsylvania where the
3 neurosurgeon is excluded, obviously that radiation
4 oncologist used NRC rules to not agree.

5 When a neurosurgeon in California doesn't
6 have to be there, because under NRC rules they're not
7 asked to be there and they can leave, you can see what
8 happens to patient safety when the wrong nerve is
9 treated.

10 So rules and regulations are to be used by
11 all. They are not to be interpreted here and there
12 and we hope that everything turns out okay.
13 Obviously, most of the time it does turn out okay.
14 The point of rules and regulations is to try to have
15 society mandate 100 percent compliance and that
16 patients are the ones to benefit.

17 So I don't want -- we don't want a
18 situation where we're going to hope the radiation
19 oncologist allows the surgeon to be a participant. We
20 want a law that tells them that the neurosurgeon needs
21 to be a participant.

22 MEMBER NAG: This is not a question, but
23 a comment. You said that single dose, single high
24 dose radiation is not often used by radiation
25 oncologists and I wish to point out that that's not

1 true, that something called interoperative radiation
2 therapy that I do every day where we give more than
3 1,000 centigrade single shot to very localized needle.
4 We operate high dose rate brachytherapy, where similar
5 dose is the one used in radiosurgery. So they are
6 done by radiation oncologists every day.

7 DR. KONDZIOLKA: Not in the brain.

8 MEMBER NAG: Not in the brain unless you
9 are using intraoperative high dose brachytherapy.

10 DR. KONDZIOLKA: And not at these doses.
11 Intraoperative high dose brachytherapy is not at these
12 doses.

13 MEMBER NAG: Very close. They are
14 quibbling about a few --

15 CHAIRMAN MALMUD: Yes, Dr. Williamson.

16 MEMBER WILLIAMSON: Is having a four-month
17 rotation in gamma stereotactic common for
18 neurosurgical residencies? How many residency
19 programs have such a requirement?

20 DR. KONDZIOLKA: Well, I would say that
21 the answer to that is not common. What the American
22 Board mandates is formal training and exposure to
23 radiosurgery and programs are asked to interpret that
24 as they see fit. Some places have one or two months.
25 Some places have not a formal time block, but then

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1 it's averaged in terms of case exposure over seven
2 years. So each institution studies that
3 independently.

4 MEMBER WILLIAMSON: But there is no case,
5 minimum case requirement or required?

6 DR. KONDZIOLKA: That's a very good
7 question.

8 MEMBER WILLIAMSON: Within your LCMG.

9 DR. KONDZIOLKA: Right, and you would be
10 surprised to know that, in fact, there's no minimum
11 case requirement for open brain surgery either.
12 Unfortunately, the educational boards cannot mandate
13 a minimum case requirement for anything. That's kind
14 of antitrust law because if a guy does -- sees 25 or
15 27, the federal government can't say what is enough of
16 anything?

17 MEMBER WILLIAMSON: One more question.
18 Many radiation oncology departments have Linac-based
19 radiosurgical or even fractionated stereotactic
20 radiotherapy programs.

21 Do you consider such training to be
22 inapplicable to gamma knife procedures?

23 DR. KONDZIOLKA: No, I consider that to be
24 good. So just because you have a gamma knife, doesn't
25 mean -- it's a tool. And certain hospitals have

1 certain other kinds of surgical tools and you learn
2 what you see, so having a background in Linac
3 radiosurgery is excellent to prepare you for eventual
4 training with the gamma knife and you'll learn to use
5 another tool, but the principles of patient selection,
6 anatomy, dose selection, they're all the same for any
7 of these devices.

8 MEMBER WILLIAMSON: Do you feel there's a
9 similar problem with the inclusion of neurosurgeons in
10 x-ray-based stereotactic radiosurgery?

11 DR. KONDZIOLKA: What do you mean by x-
12 ray-based?

13 MEMBER WILLIAMSON: Linac-based,
14 artificially, electronically produced x-rays which can
15 be used, either proton irradiation or more commonly a
16 modified Linac would be used for this purpose.

17 Is there a corresponding problem in your
18 mind?

19 DR. KONDZIOLKA: There is.

20 MEMBER WILLIAMSON: With the involvement
21 of neurosurgeons in that modality as well?

22 DR. KONDZIOLKA: There is. There is
23 actually in some ways even a stronger problem in that
24 sphere because since the Linac accelerator is part of
25 the radiation oncology set up, the neurosurgeon's role

1 is almost to be invited into another world and in the
2 gamma knife situation where the device is put in
3 almost as a separate type facility, it tends to be a
4 much more neutral kind of thing.

5 MEMBER WILLIAMSON: Are you familiar with
6 the medical policy statement of the U.S. NRC?

7 DR. KONDZIOLKA: I couldn't quote it for
8 you.

9 MEMBER WILLIAMSON: Are you familiar, I
10 mean you understand it makes a fundamental distinction
11 between I guess what is the practice of medicine and
12 what is the domain of --

13 DR. KONDZIOLKA: Of the NRC.

14 MEMBER WILLIAMSON: Of the NRC, in terms
15 of its regulatory --

16 DR. KONDZIOLKA: Oh sure.

17 MEMBER WILLIAMSON: And the general
18 assumption, is and I can't quote it to you word for
19 word, but the implication is is that patient selection
20 and selection of absorbed dose and all of these issues
21 are basically part of the practice of medicine and
22 NRC's compromise to basically include the patient as
23 a member of the public that is to be protected is to
24 limit their domain of regulatory scrutiny to ensure
25 that the written directive is followed.

1 So we tend to focus most of our discussion
2 on rules that guide the licensee in ensuring or
3 maximizing the likelihood that the written directive
4 is followed properly and that the administered dose of
5 radiation medicine is in agreement within a certain
6 tolerance with the written directive and we tend not
7 to get involved in disputes over what is the proper
8 way to write a written directive, what is the proper
9 way to select patients, what is the proper way to
10 select the absorbed dose level.

11 So I'm wondering if you have any comment
12 on this problem with respect to the medical policy
13 statement?

14 DR. KONDZIOLKA: When an NRC regulation
15 allows a situation to concur where an error arises,
16 then I think that should be of interest to the NRC.

17 So, for example, when the wrong nerve gets
18 treated, therefore that was not meant to be where the
19 radiation was to be absorbed, so that's an absorbed
20 dose problem, even though the prescription said we
21 plan to give 90 gray over there and that's actually
22 what was delivered, but in the real world, come on.
23 I mean the radiation was supposed to be over here.
24 That's a misadministration. And when that can happen
25 under NRC rules where the surgeon doesn't have to be

1 there, I think that should be of interest to the NRC.

2 So we don't live in a vacuum. I
3 understand the difference between medical care and the
4 interests of the NRC, but these rules do come
5 together.

6 Yes?

7 MEMBER RAIZNER: Just a question.
8 Assuming there was a mechanism for neurosurgeons to
9 become authorized users, and I haven't heard a
10 proposal to that effect, but assuming that that would
11 be the case, is it your position or the organization's
12 position that the written directive should be signed
13 by both the neurosurgeon authorized user and the
14 radiation oncology authorized user or either or?

15 DR. KONDZIOLKA: No. By all three. As I
16 said, we've just finished our 7,000th procedure.
17 Every directive we've ever done has been signed by the
18 neurosurgeon, the radiation oncologist and the medical
19 physicist. So it's not a matter of selecting or
20 excluding. We want to include the strengths of all
21 these individuals in every case and have all of them
22 sign off on.

23 CHAIRMAN MALMUD: Any other questions for
24 our guest?

25 Dr. Eggli?

1 MEMBER EGGLI: One question, sir. What is
2 the magnitude of the denominator? The errors seem to
3 be relatively small, albeit our goal with
4 administering therapeutic doses of radiation is that
5 we should approach zero, as close to zero as we
6 possibly can. What's the magnitude of the problem?

7 DR. KONDZIOLKA: That's a good question.
8 In fact, when I was talking on the phone to the person
9 who will speak after me, a couple of weeks ago he
10 said, well, they're not going to change anything
11 because the denominator, who knows what the
12 denominator is. You have to show some science to say
13 that we have a problem before we go fix the problem.

14 I said let me tell you about a certain
15 number of anecdotal cases that I've mentioned today.
16 He goes well, those are real big problems.

17 And so I don't know what the denominator
18 is, but the slippery slope here is that the NRC
19 guidelines for years were actually quite, you know, I
20 think excellent. And I was an authorized user. And
21 it was because that I had applied to become one and I
22 showed evidence of a huge experience in this area and
23 then the laws changed and that was taken away and I
24 don't really know why, but it was taken away.

25 And so the slippery slope is that now when

1 these facilities are showing up at medical centers
2 where credentialling issues are not so paramount,
3 self-standing facilities, I think we need to be very
4 concerned about that.

5 MEMBER EGGLI: How many radiosurgery
6 procedures are done in the U.S. annually, did you say?
7 I missed that number.

8 DR. KONDZIOLKA: I didn't give that
9 number, but many thousands. I mean we're talking, I
10 don't know, 25,000, 30,000, I guess.

11 MEMBER EGGLI: Okay, does staff have an
12 idea of how many events have been reported?

13 MR. ESSIG: Not off the top of my head.
14 I am not sure if anybody else does.

15 MEMBER LIETO: In the last 10 years, I
16 think there has been about 34 events that have been
17 reported, the NMED.

18 MEMBER EGGLI: So it's three to four a
19 year, roughly. With an N of 20 or 30,000,
20 potentially. I'm just trying to understand.

21 (Off the record.)

22 MR. ESSIG: If a person will raise their
23 hand, I'll provide the microphone to you, since this
24 appears to be the only one that's working.

25 MEMBER RAIZNER: I have a little bit of a

1 comment in that I'm witnessing sort of the deja-vu
2 several years ago. We went through the same process
3 and thinking as you're going through now in a field
4 that was being developed by the cardiologists, but in
5 which we were essentially barred by regulation to
6 administer the treatment that we were proposing and
7 advancing.

8 One of the things that we experienced when
9 all the approvals were in, that is, the intervascular
10 brachytherapy was approved, and mandated by the FDA
11 that it be a team approach, not the NRC, but the FDA,
12 that it be a team approach, one of the things that we
13 found when it became mainstream is that the enthusiasm
14 of those that were involved in its development wasn't
15 transmitted to the mainstream of cardiologists who
16 were very happy doing their part of the procedure, but
17 did not want to go to the trouble of learning all
18 about radiation physics and radiotherapy and all of
19 the things, the knowledge base that was required to be
20 a legitimate, authorized user, albeit even in the
21 restricted field.

22 I wonder if your contact with the
23 mainstream of neurosurgeons is shared by the other
24 organizations. I fully expect that you as one of the
25 leaders of this would feel that way very legitimately.

1 Is this a feeling that is diffused throughout the
2 neurosurgical profession?

3 DR. KONDZIOLKA: Yes, it's very much
4 diffused through it. In fact, it's growing so rapidly
5 within the neurosurgical profession that probably last
6 year the number of patients who had an open operation
7 for acoustic neuroma brain tumor has now been eclipsed
8 by the number of patients being radiated. And so the
9 lines have crossed.

10 So this is -- we are redefining surgery
11 here and since the alternative to virtually all of
12 this is to open the head, and if we have a viable,
13 safe, effective choice, the patients don't want their
14 heads opened. And so this is no leaving neurosurgery,
15 it's a procedure created by neurosurgeons. All the
16 Linac devices and gamma knife devices have been
17 created by neurosurgeons with physicists, not by
18 radiation oncologists. They created this alternative
19 to craniotomy.

20 I think one difference from the cardiology
21 example is that in the cardiology example, there were
22 no radiation oncologists who were going to start doing
23 angiograms. So the cardiologist still was doing
24 everything, but maybe didn't want to learn the
25 radioactive seed part at the end.

1 But here, we're talking about a complete
2 procedure whereas the federal rules exist at present,
3 can be taken over by somebody else who is really not
4 trained to do it.

5 MEMBER WILLIAMSON: I have a question for
6 the staff. Could you clarify what the previous
7 counterpart of 35690 stated regarding credentials for
8 authorized user? I have been looking at subpart J
9 which I understood reiterated essentially the old
10 training and experience requirement and I see no
11 mention in it of surgery.

12 MS. HOLAHAN: Trish Holahan, NRC. It
13 wasn't exactly in 35690. It was done by license
14 condition for gamma knives because gamma knives
15 weren't identified as a modality in the previous Part
16 35. So we did it by license condition and had an
17 authorized neurosurgeon, an authorized user and an
18 authorized medical physicist.

19 MEMBER EGGLI: The approach taken by
20 cardiology is simply to develop training programs
21 which met the training and education requirements of
22 the Nuclear Regulatory Commission. Has the
23 Neurosurgical Specialty Board considered adding enough
24 requirements to satisfy the training and education of
25 Subpart 690 to the programs?

1 And I guess the second question is, the
2 other thing that NRC does is looks at equivalent
3 experience and when the staff looks at an application
4 for authorized user status with equivalent experience,
5 if it doesn't meet the regulation per the letter of
6 the regulation, but looks good, one of the things that
7 the staff often does is refers it to this Committee to
8 look at training credentials, to advise staff on
9 whether the training is similar enough that their
10 Committee could endorse that equivalent training.

11 It seems that if you get your authorized
12 user status that nobody can lock you out essentially,
13 because I don't think NRC is locking you out, that
14 there is a club being used and NRC doesn't seem to
15 require it. But is there anything that precludes you
16 from submitting your credentials and asking for
17 authorized user status on an equivalency of experience
18 and training basis?

19 DR. KONDZIOLKA: Thanks, well about 1994
20 I did just that and I was put on the license and
21 granted to be an authorized user. So about two years
22 ago that was taken away.

23 MEMBER EGGLI: I think that was not an
24 actual authorized user status based on what Dr.
25 Holahan said that it was in fact an institutional

1 license where, in fact, particular credentials could
2 be submitted to Region 1.

3 DR. KONDZIOLKA: To answer the first
4 question about neurosurgery's training of would
5 neurosurgery be open to that and at every
6 neurosurgical meeting there are hours spent on
7 radiosurgery, practical courses and so on. But this
8 is not what you're talking about. These are courses
9 that are really introductions to the technique and
10 what the technology is. I guess neurosurgery is open
11 to anything. They'd have to look at what those are
12 and if it was of interest, I think it could be done.

13 My Radiation Safety Officers here, you can
14 probably tell me better as to what kind of license or
15 authorized user status I actually had, but anyway,
16 that's --

17 MEMBER EGGLI: The bar is set in Subpart
18 690 and if neurosurgeons as an organization chose to
19 hit that bar, then it would seem that you would have
20 no difficulty getting authorized user status. And I
21 guess that's one of the things that is always looked
22 at is sort of where is the bar? What's the minimum
23 level where that bar is set and I think the process is
24 a fair one. I'm not always happy what the bar is, but
25 I know if I hit that bar, then I have the necessary

1 credential.

2 MR. SHEETZ: Hi, Mike Sheetz, University
3 of Pittsburgh. If I can give some clarification, we
4 were the first gamma knife license in the United
5 States and because of our neurosurgery involvement we
6 created this team concept where we have a
7 neurosurgeon, radiation oncologist and medical
8 physicist all involved in patient treatments. And so
9 the neurosurgeon was named on the license as an
10 equivalent authorized user, I guess by license
11 condition. And so with respect to the training and
12 experience requirements for 35600, it requires a
13 residency program in radiation oncology. The
14 neurosurgery residency programs right now are seven
15 years. So to add another three years to that would be
16 a long time before a neurosurgeon would meet the
17 requirements of an authorized user radiation
18 oncologist.

19 MEMBER WILLIAMSON: I believe the
20 alternate pathway in 35490 and 690 requires explicitly
21 the residency in radiation oncology for three years,
22 but not board certification.

23 DR. ZELAC: As you know, 690 has recently
24 been revised. It is not yet effective, but will be at
25 the end of the month. And the alternate pathway for

1 690 approval requires three years of supervised
2 clinical experience in radiation therapy. It's not a
3 residency, it's three years of supervised clinical
4 experience, plus the specific 200 hours and 500 hours
5 for classroom and laboratory and for work experience.

6 DR. KONDZIOLKA: Well, from the patient
7 perspective, I would just tell you that that kind of
8 training is not uniformly adequate for the radiation
9 oncologists who are practicing in the United States
10 for doing this procedure.

11 CHAIRMAN MALMUD: If I may, we had a side
12 conversation during the period of silence and I asked
13 what his concerns were and one is that -- one concern
14 is that non-neurosurgeons are providing this therapy
15 which concerns him in terms of patient safety. That's
16 one issue.

17 It's my belief that that is not an NRC
18 issue, but that's a patient credentialing issue of
19 some sort, but we can sort that out later. We don't
20 have to tie you up for us to clarify that issue.

21 And the second issue is the desire for the
22 radiation oncologist to not have to remain in the
23 procedure room during the radiation therapy, meaning
24 during the stereotactic radiosurgery. But that there
25 is a desire on your part that the team approach be

1 used of having three authorized users present: the
2 neurosurgeon, the radiation oncologist and the
3 radiation physicist. And at the moment, the
4 neurosurgeon is not identified as an authorized user.

5 Did I summarize what your goals are?

6 DR. KONDZIOLKA: Yes.

7 CHAIRMAN MALMUD: I just wanted to get
8 that on the record.

9 MEMBER RAIZNER: But let me also make sure
10 I understand the record as to what a neurosurgeon
11 could do to become an authorized user. And what I
12 understand is that he would have to do three years of
13 radiation oncology training, residency training, in
14 addition to the 200 hours of laboratory and could
15 somebody clarify if a neurosurgeon wanted to become an
16 authorized user, what is the exact and specific
17 special training that he would have to go through?

18 MS. HOLAHAN: This is Trish Holahan. It's
19 not specific to radiation oncology, it's radiation
20 therapy. We made that change in the revised Part 35.

21 MEMBER RAIZNER: So he would -- he or she
22 would have to do three years of radiation therapy?
23 Please clarify that.

24 Is it a number of hours of didactic, a
25 number -- what --

1 CHAIRMAN MALMUD: If I understood what was
2 just read to us a few minutes ago, it's that the
3 neurosurgeon would require three years of experience
4 in radiation therapy.

5 Does that mean three years of training?
6 And that's a question that I'm asking of the NRC
7 staff. Does someone from the NRC feel free to respond
8 to that question?

9 Dr. Zelac?

10 DR. ZELAC: Thank you. Specifically, the
11 alternate pathway has the following requirements: 200
12 hours of classroom and laboratory training in the
13 following areas: radiation physics and
14 instrumentation, radiation protection, mathematics
15 pertaining to the use of measurement of radioactivity
16 and radiation biology; 200 hours in those subjects.
17 Plus, 500 hours of work experience involving the
18 following subjects: reviewing full calibration
19 measurements and periodic spot checks; preparing
20 treatment plans and calculating treatment times and
21 doses; using administrative controls to prevent a
22 medical event; implementing emergency procedures to be
23 followed in the event of abnormal operation; checking
24 and using survey instruments and selecting the proper
25 dose and how it is to be administered.

1 So that's 500 hours of work experience in
2 those subjects. And I should point out as well, that
3 those 500 hours are to be received under the
4 supervision of an authorized user.

5 Third, the requirement is completion of
6 three years of supervised clinical experience in
7 radiation therapy under an authorized user. As part
8 of a formal training program approved by the Residency
9 Review Committee for radiation oncology, so I stand
10 corrected, I just didn't turn the page. This
11 experience may be obtained concurrently with the
12 supervised work experience.

13 And finally, and most importantly from our
14 perspective, has obtained written attestation that the
15 individual has satisfactorily completed these various
16 requirements and has achieved a level of competency
17 sufficient to function independently as an authorized
18 user for the type of therapeutic unit for which the
19 individual is requesting authorized user status.

20 CHAIRMAN MALMUD: Thank you for clarifying
21 that, Dr. Zelac.

22 So for a technically -- if I understood
23 you correctly, for a neurosurgeon to achieve
24 authorized user status, he or she would have required
25 200 hours of classroom and lab experience, plus 500

1 hours of work experience involved in the areas that
2 you mentioned under the supervision of an existing
3 authorized user and then, in addition to that, or
4 three years of clinical experience under an authorized
5 user as part of a formal program in radiation
6 oncology.

7 I assume that the 200 hours and 500 hours
8 could have been achieved under that three-year program
9 in radiation oncology and the answer is yes, from
10 nodding of the heads of the NRC Staff.

11 So essentially, it boils down to three
12 years of experience in a rad.onc program. That's the
13 alternate at the moment. Thank you.

14 I want to thank you for your input and we
15 have another speaker and therefore, we'll move on.
16 Thank you very much.

17 Our next presentation will be made by Dr.
18 David Larson, the former chairman and professor of
19 radiation oncology and neurology at the University of
20 San Francisco. And Dr. Larson will be talking about
21 the importance of radiation oncology presence and
22 authorized user status for gamma knife stereotactic
23 procedures.

24 Dr. Larson?

25 DR. LARSON: Is this working okay? Good

1 afternoon. I'm Dr. David Larson from the University
2 of California, San Francisco.

3 I appreciate the comments of Dr.
4 Kondziolka who I've known for years and I have respect
5 for his scientific and clinical credentials as a
6 neurosurgeon.

7 He's currently the president of the International
8 Stereotactic Radiosurgery Society, a scientific
9 organization which is not the same as IRSA, the
10 International Radiation Support Association which is
11 a trade organization.

12 I'm past president of that same scientific
13 body, IRSA. I'll mention I have a Ph.D. in high
14 energy physics as well as an M.D. I'm a professor of
15 Radiation Oncology at UCSF and I have an appointment
16 in the Department of Neurosurgery at UCSF. I'm a
17 nonpaid scientific advisor of the Elekta Scientific
18 Board. Elekta makes the gamma knife. I'm a nonpaid
19 board member of the CyberKnife Society, a Linac-based
20 competing device.

21 And with me today is Dr. Paul Wallner,
22 currently senior vice president of 21st Century
23 Oncology, previously chief of the Clinical Radiation
24 Oncology Branch of the National Cancer Institute and
25 professor and vice chairman of the Department of

1 Radiation Oncology at the University of Pennsylvania
2 School of Medicine.

3 So on behalf of the American Society for
4 Therapeutic Radiology and Oncology, ASTRO, we
5 appreciate the opportunity to respond to a letter
6 recently submitted to the NRC by the International
7 Radiosurgery Support Association, IRSA, regarding the
8 administration of radiosurgery using gamma
9 stereotactic radiosurgery units which I will just
10 abbreviate and call GSR.

11 In addition to the oral statement that we
12 will give at this time, ASTRO has submitted written
13 testimony that explains our position in greater
14 detail.

15 ASTRO is the largest radiation oncology
16 society in the world with more than 8,000 members who
17 specialize in treating patients with radiation
18 therapy.

19 ASTRO has long maintained collegial,
20 cordial and clinically cooperative relationships with
21 neurosurgeons for the administration of GSR since the
22 inception of the procedure.

23 These relationships continue to be
24 maintained by a majority of radiation oncologists and
25 neurosurgeons. This position was stated formally in

1 1993 and 1994 by documents jointly signed by authors
2 from ASTRO task forces, an ASTRO task force and AANS,
3 American Association of Neurologic Surgeons Task
4 Force.

5 This position was again emphasized in 1997
6 and 2002 in American College of Radiology guidelines
7 that were written with the help of ASTRO members.

8 Recently, ASTRO, AANS and CNS, Congress of
9 Neurologic Surgeons affirmed that single fraction
10 stereotactic brain radiosurgery should be performed by
11 both neurosurgeons and radiation oncology
12 participants.

13 Currently, ASTRO members are working with
14 the American College of Radiology to update
15 radiosurgery guidelines.

16 Unfortunately, as a result of many gross
17 representations made by IRSA, an organization which
18 developed initially as a gamma knife neurosurgery and
19 patient support organization, not a medical society,
20 we feel compelled to comment for the record.

21 ASTRO supports the current regulations as
22 implemented by the NRC for gamma radiosurgery and we
23 believe that the measures put in place by the
24 Commission promote safety and high quality patient
25 care.

1 We also have reason to believe that the
2 gamma knife manufacturer and the vast majority of
3 neurosurgeons also support the existing regulations.
4 Current regulations are appropriate and adequate and
5 promote public and patient safety and high quality
6 patient care.

7 ASTRO absolutely agrees that the
8 authorized user and the authorized medical physicist
9 must be physically present throughout all patient
10 treatments involving GSR.

11 Medical use of radioisotopes is a complex
12 and potentially dangerous process that demands the
13 cooperation of a team of trained professionals in
14 order to ensure high quality and safe administration
15 to the patient. And minimal exposure to medical
16 personnel. The radiation oncologist has the principal
17 responsibility to determination the radiation
18 treatment and to oversee its implementation to ensure
19 patient and staff safety.

20 The GSR team is composed of the
21 neurosurgeon, radiation oncologist, medical physicist
22 and radiation therapist. Radiation oncologists are
23 and should remain one of the two leaders of the team.
24 Radiation oncologists must remain the authorized
25 users, considering their comprehensive training to

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1 handle all aspects of treatment planning, delivery and
2 safety of medical radiation sources for such medical
3 procedures.

4 ASTRO objects to issues raised in the IRSA
5 submission that question the vital importance of the
6 authorized medical physicist during gamma stereotactic
7 surgery which clearly demonstrate a lack of knowledge
8 of the vital role played by the AMP and GSR. The
9 medical physicist is essential in ensuring safety as
10 stated in the 1993 and 1994 joint documents as well as
11 in the 1997 and 2002 ACR guidelines documents.

12 IRSA correctly contends that it is of
13 paramount importance to carefully match the dose of
14 radiation delivered to a precise location, thus
15 limiting the radiation delivered to the surrounding
16 brain. The essentials for training in radiation
17 oncology, as stated by the ACGME, require radiation
18 oncology trainees to have training and experience
19 treating all sites in the body including the central
20 nervous system and they're required to learn about the
21 treatment of both malignant and benign diseases.

22 Radiation oncology residents are expected
23 to learn neuroanatomy, neuroradiology and neurological
24 functionality. The American Board of Radiology
25 certification examinations and radiation oncology

1 provide questions in all of these areas on both the
2 written and oral portions of the examinations.

3 While ASTRO concurs that the neurosurgeon
4 is an integral part of the patient's selection,
5 treatment and decision making process, once the
6 patient has arrived in the GSR center for actual
7 treatment, target and critical structure delineation
8 has already occurred and been agreed upon. The
9 assertion that the risk of permanent neurological harm
10 will be increased if a radiation oncologist
11 administers the treatment alone is patently ludicrous.

12 Radiation oncologists determine target and
13 normal tissue volumes and prescribe and deliver doses
14 of radiation to every part of the body without the
15 benefit of other specialists' direct oversight as a
16 matter of routine daily practice.

17 Radiation oncologists are required to
18 understand normal tissue toxicity for all
19 fractionation schemes, including one.

20 The designation of neurosurgeons as
21 authorized users is inappropriate and we believe would
22 not be in the best interests of patients. The
23 neurosurgery residency program, as spelled out in the
24 ACGME essentials does not include any required
25 radiation oncology, normal radiation pathology,

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1 biology, physics, treatment planning or safety
2 components.

3 The American Medical Association's
4 graduate medical requirements state that the
5 neurosurgery program, in its broad general statement
6 of principles should include stereotactic
7 radiosurgery, but does not delineate any specified
8 number of hours, cases or level of involvement by the
9 trainee.

10 In addition, the neurosurgical board
11 certification exams have no specific stated
12 requirements for inquiry into any areas of radiation
13 oncology principles. ACGME training requirements, as
14 of 2005-2006, for neurosurgery do not mention
15 radiation, radiobiology, sealed or unsealed sources,
16 normal tissue tolerance, radiation effects, treatment
17 planning or any radiation producing device or source.

18 ASTRO absolutely disagrees that it is
19 commonplace for the radiation oncologist to leave for
20 other clinical duties during GSR administration and
21 unequivocally rejects the practice, if it occurs.

22 As with other high risk procedures, the
23 radiation oncologist will remain within a reasonable
24 proximity to the patient undergoing therapy as
25 mandated in the federal regulations.

1 ASTRO believes that the best training in
2 radiosurgery is acquired through the four-year
3 residency program and specialty board certification
4 program. Although ASTRO does not object to vendor-
5 sponsored training classes, the society believes that
6 the totality of training acquired in a radiation
7 oncology residency program better equips a radiation
8 oncologist to perform radiosurgery procedures safely.

9 As noted by IRSA, Dr. Lars Leksell, a
10 pioneer in the field, called a single high dose of
11 radiation delivered stereotactically to discrete
12 target in the brain, stereotactic radiosurgery. ASTRO
13 agrees with this. Radiosurgery is simply one form of
14 radiation therapy.

15 There are two main techniques for the
16 delivery of stereotactic radiosurgery in wide use in
17 the United States. The Cobalt-60 gamma radiosurgery
18 units, GSR, and linear accelerator base radiosurgery
19 units. Both types of units may be used for single
20 dose or fractionated therapy. Both may require the
21 placement of an immobilization device or head frame.
22 Both require precise delineation and localization of
23 target and normal tissue volumes. And both allow the
24 delivery of highly focused ionizing radiation to spare
25 surrounding normal tissues.

1 There is no clinically demonstrated
2 superiority in either precision or treatment outcomes
3 of the Cobalt-60 GSR units over Linac-based units.
4 There have been two large randomized studies, both
5 investigating whole brain radiotherapy plus or minus
6 radiosurgery published in 2004, one involving patients
7 with metastatic tumors in the brain, one involving
8 patients with glial blastomas.

9 The outcome of the radiosurgery arm in
10 each case was not device dependent. ASTRO objects to
11 the assertion that the issue of ownership and NRC
12 licensing are related. ASTRO does not believe that
13 non-hospital-based ownership of GSR units is improper
14 as long as such facilities can meet the same stringent
15 NRC guidelines for appropriately licensed personnel,
16 safety, source security and quality assurance as
17 hospital-based units.

18 ASTRO also believes that hospitalization
19 of GSR patients on a routine basis is not clinically
20 or economically supportable and disputes the fact that
21 safety oversight in the hospital setting is any more
22 rigorous.

23 It is evident that only radiation
24 oncologists possess the specialized training and
25 experience that is vital to carrying out all oversight

1 and safety procedures governed by the NRC regulations.
2 The educational and training program as set forth by
3 the Accreditation Council for Graduate Medical
4 Education ensures that radiation oncologists are
5 thoroughly trained in all aspects of radiation therapy
6 treatments.

7 Dr. Kondziolka may have little
8 appreciation of the training and experience of
9 radiation oncologists. He did mention the multi-
10 institutional media temporal lobe epilepsy gamma knife
11 study that was initiated at the University of
12 California by one of my neurosurgery colleagues and
13 for which I'm a co-investigator.

14 I'll just say a few technical things about
15 that study. Using gamma knife for medial temporal
16 lobe epilepsy is investigational. It's currently not
17 reimbursed because it is investigational. And this is
18 an attempt to gather data in a rigorous manner.

19 So this was multi-institutional and we
20 selected the very best epilepsy and neurosurgery
21 programs in the country who also had expertise in
22 gamma knives. So these were true experts who were
23 participating involving radiation oncologists,
24 neurosurgeons and physicists.

25 On the day of treatment, the plan was

1 required to be sent electronically to UCSF for quality
2 control and once we looked at the plan, we could then
3 phone back the institution and say make an adjustment
4 in the plan or go ahead with treatment.

5 What we found was that dispute all of the
6 years of training of the neurosurgeons and despite a
7 written protocol and dispute meeting with them and
8 defining what the anatomic boundaries were and half
9 the cases, if the treatment would have been carried
10 out as it was designed and sent to us, we would have
11 had complications. We would have had some cases of
12 blindness. We would have brainstem damage.

13 I, a simple radiation oncologist, saw all
14 of these, along with my neurosurgery colleague, Dr.
15 Barbero, called up the institutions and said make an
16 adjustment and if you make the appropriate adjustments
17 we'll go ahead and treat.

18 In some cases, the adjustments were made
19 three or four times until it met the requirements of
20 the protocol, despite all of the neurosurgery training
21 we've heard about.

22 At many gamma knife centers in the United
23 States, the neurosurgeon leaves after the procedure
24 starts or does not show up for the procedure. As far
25 as I know, the neurosurgeon does put the stereotactic

1 frame on. At my institution, I often take the frame
2 off.

3 We don't have a requirement at my
4 institution that the neurosurgeon be there. We do
5 have a requirement that I be there and I am there.

6 The radiation oncologists, throughout the
7 United States, have the obligation to understand
8 emergencies and have the ability to treat routine
9 emergencies. This is not something that only a
10 neurosurgeon can do. This is something that happens,
11 occasionally in my department, once or twice a year.
12 It's something that I can handle.

13 Medicines are given by radiation
14 oncologists, not just neurosurgeons. That's routine
15 in my hospital. It's routine in many.

16 It was mentioned earlier by Dr. Kondziolka
17 that the doses given in radiosurgery are much higher
18 than what a radiation oncologist might give in normal
19 practice. One of the Committee Members mentioned
20 brachytherapy. I'll just state that I routinely give
21 brain, permanent brachytherapy doses of 70,000
22 centigrade. These are very high doses. These are
23 very high doses. I do this without the supervision of
24 a neurosurgeon. A neurosurgeon is present to make a
25 surgical cavity at which time we place the sources.

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1 There's no other specialty that possesses
2 the skill, knowledge or expertise in radiation therapy
3 procedures that is currently held by radiation
4 oncologists. Therefore, it is imperative that the NRC
5 deny state licensure resumptions that designate an
6 authorized user other than the radiation oncologist
7 for GSR. The allowance of such exemptions could
8 result in poor quality health care, inappropriate
9 radiation exposure, unsafe working conditions and a
10 significant increase in the probability of medical
11 errors.

12 Gamma knife is an alternative to surgery
13 as has been mentioned. It's also an alternative to
14 standard radiotherapy.

15 Excuse me. Dr. Kondziolka characterized
16 my response regarding a recent phone conversation in
17 which he mentioned some misadministration as perhaps
18 being cavalier. Those are my words. I just want to
19 assure the Committee that that is entirely false, if
20 that is your impression, I would decry any
21 complication.

22 We heard about the numbers of
23 complications. I believe the number of patients
24 treated with gamma knife in the year is now somewhat
25 over 20,000. Five years ago it was somewhere between

1 15,000 and 20,000. So in the last five years,
2 certainly a 100,000 patients have been treated with
3 gamma knife, just to mention the denominator that
4 people were asking about a little while ago.

5 ASTRO does not dispute the fact that a
6 specific institution or a specific neurosurgeon may
7 possess unique or even excellent background training
8 and experience, but the purpose of generally
9 promulgated regulations should not and cannot be
10 guided by these outliers from the norm.

11 In addition, facility management,
12 equipment and personnel change on a regular basis and
13 regulations must be promulgated for the continuing of
14 care. Therefore, we respectfully request that the NRC
15 deny the changes requested for inclusion of
16 neurosurgeons as authorized users under 35.690.

17 We would be happy to answer any questions
18 and expand on our comments. Thank you.

19 CHAIRMAN MALMUD: Thank you, Dr. Larson.
20 Are there questions for Dr. Larson?

21 Dr. Vetter?

22 MEMBER VETTER: Thank you for that very
23 excellent, well-organized presentation.

24 Just a question to clarify, both the
25 radiation oncologists and the neurosurgeon agree on

1 the coordinates for the setting the patient, to put
2 the patient on the machine, prior to placing the
3 patient on the machine. And both are qualified to
4 assure that those coordinates are set properly prior
5 to treatment.

6 DR. LARSON: Yes, that's correct. And
7 regarding signing a written directive, of course, the
8 radiation oncologist always signs the written
9 directive. Now at my institution, the neurosurgeon
10 also signs the written directive and I think that's
11 probably true for Linac radiosurgery and gamma knife
12 radiosurgery at all institutions in the United States.
13 At least that would be the standard of care.

14 CHAIRMAN MALMUD: Dr. Wallner?

15 DR. WALLNER: I'd just like to make two or
16 three very brief comments in addition to Dr. Larson's
17 comments.

18 First of all, I think the fact that a
19 trade organization and several individual
20 neurosurgeons have petitioned for a change in Part
21 35690 demonstrates the basic lack of understanding of
22 the entire authorized user issue.

23 We have never -- we, ASTRO, speaking
24 officially for ASTRO, have never suggested that
25 neurosurgeons should not be a part of stereotactic

1 radiosurgery and if there is an institution or
2 facility that is doing it in the absence of a
3 neurosurgeon, I decry that practice.

4 That is a credentialling and privileging
5 issue. That is not an NRC safety issue. The issue of
6 the authorized issue concept is to protect the safety
7 of the patient and the safety of the staff, vis-a-vis,
8 radioactive materials and only that. That's the
9 mandate and mission of the NRC.

10 The fact that a request has been made to
11 change the authorized user designation and definitions
12 simply because quote some people want to do that or
13 think they're trained to do that, I think is demeaning
14 to the entire process.

15 The other issue that I'd like to make is
16 having served as a program director in radiation
17 oncology and as a board certification examiner in
18 radiation oncology, I completely disagree with Dr.
19 Kondziolka's remarks regrading the training and
20 qualifications of individuals trained in radiation
21 oncology. That is insulting and demeaning to an
22 entire specialty and I think we should focus simply on
23 the issue of authorized user.

24 To have multiple authorized users of
25 radiation sources and we're not talking about

1 credentialling. We're not talking about clinical
2 activities. Multiple authorized users would be like
3 writing a symphony by committee. One individual
4 ultimately is responsible for the safety of the
5 radioactive sources, the radioactive safety of the
6 patient and of the staff, the one individual is the
7 authorized user.

8 CHAIRMAN MALMUD: Thank you, Dr. Wallner.
9 Dr. Eggli?

10 MEMBER EGGLI: I don't think anybody would
11 disagree that authorized user, particularly for the
12 690 uses has very strong requirement associated with
13 the skill and training level associated with it.

14 The alternate pathway in some of the areas
15 of the regulation are designed to allow someone who
16 doesn't go down a board certification pathway to
17 demonstrate competence and submit credentials.

18 In part 690, 690 not only specifies the
19 body of knowledge which must be mastered, but who can
20 purvey that body of knowledge which is different than
21 part 190, part 290 and part 390 and it may be that
22 there are special reasons for that, but the reality is
23 there is no real alternate pathway here. And you must
24 go down the recognized board certification pathway and
25 again, I think an authorized user has a bar they must

1 go over. But in 690, we say who can provide that
2 training and who can't, not what the content of that
3 training is.

4 CHAIRMAN MALMUD: Any other comments?
5 Hearing none, we'll take a break. At this time we
6 hope to get back at 3:10. I'll be here.

7 (Off the record.)

8 CHAIRMAN MALMUD: It's 10 after 3 and if
9 we may, we will resume for the afternoon session.
10 Thank you.

11 This is an open session and the topic is
12 the physical presence during gamma stereotactic
13 radiosurgery. And we have presenters from IRSA and
14 ASTRO.

15 Does anyone wish to begin? Yes, please.

16 MR. RAGLAND: Hi, my name is Randy
17 Ragland. I'm an NRC Inspector from Region 1. And our
18 rules for physical presence are contained in 10 CFR
19 35615(f)(3) and they specify physical presence for the
20 AMP and the AU throughout the procedures for gamma
21 stereotactic radiosurgery.

22 And we were prescriptive in that to ensure
23 the correct delivery of dose and emergency response.
24 And we have a definition in the statements of
25 consideration that say within hearing distance of

1 normal voice. But to ensure correct delivery of dose,
2 the majority of work to ensure that comes in
3 preparation for the treatment that comes through the
4 treatment planning and the imaging and the placement
5 of the frame on the head and also in the set up of the
6 equipment. So my question is kind of for possibly the
7 neurosurgeons or Dr. Kondziolka.

8 Once the treatment starts, what actions
9 are taken to ensure correct delivery of dose and
10 emergency response. What actions -- how can the
11 neurosurgeon perform that as well as the radiation
12 oncologist or vice versa?

13 DR. KONDZIOLKA: Thank you, Randy. I
14 guess the question is how does the neurosurgeon
15 confirm correct delivery of dose during the
16 administration of the radiation? Well, the
17 neurosurgeon is trained to use stereotactic frames and
18 is trained in the coordinate system that is used to
19 aim the radiation and hook the frame up with the gamma
20 knife to the device. So there are two current methods
21 of doing this with the gamma knife. One is a manual
22 method where the coordinates, the three dimensional
23 coordinates are set on the frame using a screwdriver.
24 It's the same frame that we use in the operating room
25 for brain biopsies, placement of electrodes in

1 Parkinson's Disease and so on.

2 And so we set the coordinates up and we
3 triple check them. We published a paper on the
4 accuracy of triple checking coordinates to make sure
5 that human error is minimized and with three
6 independent checkers of the three dimensional
7 coordinate work together, the chance of being a
8 quarter of a millimeter off is calculated to be one in
9 18,000. When two people check, the chance of being a
10 quarter millimeter off, that is the second person
11 confirming it, is going to be about one in 1,800, so
12 we go for the one in 18,000 reliability and we have
13 three people verify.

14 When that is set up in the machine, the
15 frame does not move, the radiation is delivered to the
16 center of the stereotactic frame and no one else.
17 Physically can't go anywhere else and so the delivery
18 is then confirmed.

19 How do we know in an individual patient?
20 Of course, we can't actually measure it, but when we
21 look at the outcomes on how patients do the tumors
22 respond, the vascular malformations go away and the
23 lesions for Parkinson's Disease show up at exactly
24 those coordinates.

25 The other way to do it which is the

1 nonmanual mode is an automated method where the frame
2 is attached to a robotic device which is part of the
3 gamma knife helmet and when this device is attached,
4 there is a set of multiple checks that are mechanical
5 where the coordinate is then read out on a computer
6 screen on the machine. So once the coordinates are
7 set up, the computer shows us those coordinates. We
8 look at them, but then we actually have to look at the
9 frame itself and go back to the manual eye-based
10 verification system to show that what's actually
11 happening in reality is reflected on the computer and
12 then that's reflected on the computer at the gamma
13 knife treatment console. There's a multi-step way of
14 confirming that and that is how either a neurosurgeon
15 or a radiation oncologist or the physicist would
16 confirm that the dose is delivered to the right
17 location.

18 CHAIRMAN MALMUD: Thank you. Does anybody
19 else wish to comment in response to the question
20 raised by Mr. Ragland?

21 DR. LARSON: I would agree with everything
22 that Dr. Kondziolka has said in terms of what is done
23 and how it is done.

24 At my institution, we have always four
25 people at the treatment site and sometimes five. The

1 four people that are always there are radiation
2 oncologist, nurse, Ph.D. physicist, and dosimetrist
3 and the neurosurgeon is often there.

4 So all of these mechanical adjustments and
5 manipulations are performed by the radiation
6 oncologist and other people. We also always check
7 three times and then when the patient leaves the
8 machine and it's in the mechanical non-APS mode, we
9 also recheck all of the coordinates.

10 One thing to mention is that when the
11 planning is done, before treatment takes place,
12 planning has been agreed upon and signed off on by
13 neurosurgeon and radiation oncologist and physicist.
14 What is produced by computerized planning system is a
15 bunch of mechanical variables that determine the
16 position of the patient and the machine with respect
17 to the isocenter of the machine, as well as some
18 mechanical variables having to do with the plugging
19 pattern and the collimator size.

20 So there's a lot of things that need to be
21 checked. We agree that these all need to be checked
22 three times on every patient.

23 CHAIRMAN MALMUD: Dr. Diamond?

24 MEMBER DIAMOND: First, I'd like to thank
25 very much Dr. Larson and Dr. Kondziolka for coming.

1 I have tremendous respect for both of you. You've
2 done wonderful work and I congratulate both of your
3 teams.

4 Prior to today's discussion, a letter, a
5 very lengthy letter actually was submitted by IRSA to
6 the NRC as a public document dated January 31, 2005.
7 I believe the author of that letter was Mrs. Emerick
8 on behalf of IRSA and since she is the author of that
9 document, I was wondering if I could invite her up to
10 sit next to me and I have some questions for her,
11 please?

12 I have a couple of comments for her.
13 Please have a seat.

14 Thank you for coming. Please introduce
15 yourself for the transcriptionist.

16 MS. EMERICK: I'm Rebecca Emerick,
17 Director of International Radiosurgery Association.

18 MEMBER DIAMOND: You are the contact
19 person for this letter. Is that correct?

20 MS. EMERICK: Yes.

21 MEMBER DIAMOND: IRSA has a medical or
22 scientific advisory board of some sort, is that
23 correct?

24 MS. EMERICK: We have a hospital advisory
25 board, a governing board and a physician advisory

1 board.

2 MEMBER DIAMOND: Okay, do you have any
3 radiation oncologists on any of those boards at this
4 time?

5 MS. EMERICK: Yes.

6 MEMBER DIAMOND: Who are they?

7 MS. EMERICK: I don't have a list in front
8 of me, but Jonathan Knisely is one from Yale
9 University; John Flickinger from Pittsburgh; there's
10 others. I just don't have the whole list. Sandy
11 Vermillion from Seattle.

12 MEMBER DIAMOND: Okay, I've heard you. So
13 Dr. Flickinger is a member of one of your advisory
14 panels?

15 MS. EMERICK: Yes.

16 MEMBER DIAMOND: I was surprised and I was
17 not aware of it, upon coming here yesterday, there's
18 a letter dated April 6, 2005 in which Dr. Flickinger
19 is a signatory. Have you seen that letter?

20 MS. EMERICK: Just this morning.

21 MEMBER DIAMOND: You recognize that he
22 does not agree with the presentation that you have
23 made.

24 MS. EMERICK: I think he's saying
25 something else. He doesn't agree with the radiation

1 oncologist exemption. I wasn't very clear from
2 reading that and neither were several other people.
3 I can't speak to what he was saying.

4 MEMBER DIAMOND: Well, why don't I read
5 the last paragraph for you? "Our department has an
6 excellent working relationship with our neurosurgical
7 colleagues, but we do not support this application."
8 That's the first sentence.

9 MS. EMERICK: We don't have an
10 application.

11 Pittsburgh has applications in for different things
12 and I'm not sure what that paragraph was addressing.

13 MEMBER DIAMOND: I think a reasonable
14 reading would suggest that the word "application"
15 refers to the discussion at hand. But of course,
16 that's debatable.

17 In the course of your document, I think
18 you and your co-authors made about six different
19 points and I'd like to address just a few of them.
20 The first and this is on page 15 of the document that
21 you submitted and this is dated January 15, issue
22 number one, ownership and NRC licensing of GSR units.
23 In the second paragraph --

24 MS. EMERICK: Could I have a copy of that
25 document?

1 MEMBER DIAMOND: In your second paragraph,
2 I'm on page 15, Rebecca. You state "IRSA firmly
3 believes that all GSR units should be located on
4 hospital grounds." I would just like to remind you
5 that no way, no how is this the purview of the NRC
6 regarding where specifically a unit is located,
7 whether it be on hospital grounds, adjacent to a
8 hospital and it's just important that as you write
9 these documents that you recognize that there are
10 things that we input in and there are things we have
11 no input in and this is one of the areas where --

12 MS. EMERICK: I agree with you. We don't
13 know the whole purview of the NRC, but there were
14 patient safety issues we simply wanted to bring up.

15 MEMBER DIAMOND: I understand that. Do
16 you understand this has nothing to do with this,
17 right?

18 MS. EMERICK: They were listed in case
19 they did.

20
21 MEMBER DIAMOND: All right. The other
22 issue is one of the big things that this committee
23 faces and the whole NRC faces after 9/11 2001 is that
24 of public safeguards and security. In fact, we had a
25 closed briefing this morning. We take issues of

1 safeguards material extremely seriously and in the
2 second paragraph on page 15, you state that you are
3 aware of a center which IRSA "believes this center to
4 be unguarded by security."

5 Where is this place?

6 MS. EMERICK: Is there a reason I should
7 answer that? I think Region 1 knows exactly where it
8 is.

9 MEMBER DIAMOND: Well, if you know, I'd
10 appreciate knowing it.

11 MS. EMERICK: You can ask Region 1. I can
12 tell you, but I'm not here to squeal out of school.
13 That facility is a problem. It now has some minor
14 hospital ownership. Medicare has refused to pay for
15 treatments there. Blue Cross and the Department of
16 Health in Pennsylvania has taken exception --

17 MEMBER DIAMOND: We're talking about
18 safeguards of sources and anyone that comes to this
19 committee that has a concern about safeguard --

20 MS. EMERICK: That's fine --

21

22 MEMBER DIAMOND: Of Cobalt-60 sources --

23 MS. EMERICK: I don't have legal counsel
24 with me and I believe --

25 MEMBER DIAMOND: We'd like to know about

1 it.

2 MS. EMERICK: Region 1 can tell you where
3 that is.

4 MEMBER DIAMOND: It's really important
5 that if you're going to submit a document like this
6 with allegations that you go and instead of making it
7 hearsay --

8 MS. EMERICK: I did discuss the name and
9 the facility with NRC staff.

10 MEMBER DIAMOND: Is NRC staff aware of
11 where the center may be located?

12 MR. ESSIG: No, I'm not.

13 MEMBER DIAMOND: They don't seem to know.

14 DR. MILLER: That doesn't necessarily mean
15 that it wasn't discussed with NRC staff.

16 MR. ESSIG: They do.

17 MEMBER DIAMOND: I'll try to restate the
18 question. Is there currently a licensed gamma knife
19 radiosurgery center in which there is a real concern
20 that the sources may not have appropriate safeguards?

21 MS. FLANNERY: This is Cindy Flannery,
22 NRC. After review of this particular statement
23 submitted by IRSA, I met with the allegations expert
24 from NRC. We spoke to Ms. Emerick and we could not
25 treat this as an allegation because there were no

1 stated facilities and we couldn't pursue it.

2 When we met with the allegations person
3 from NRC, we could not pursue this as an allegation
4 since there were no stated facilities when we had the
5 interview with Ms. Emerick.

6 MEMBER DIAMOND: So she tell you where
7 this facility was?

8 MS. FLANNERY: Correct.

9 MEMBER DIAMOND: I'll try again.

10 MS. EMERICK: You know, it's well known in
11 Region 1. This is the Easton facility that's located
12 in a strip mall. I think our concern was the location
13 for it --

14 DR. MILLER: May I just stop the
15 proceeding for one minute since the allegations
16 coordinator for headquarters for materials facilities
17 works for me. NRC makes every effort to protect the
18 identity of allegers and if we're getting into
19 discussions with regard to allegations, we have to do
20 it through our allegation review board. We cannot do
21 it in a public forum.

22 MEMBER DIAMOND: Okay, but didn't you just
23 state Cynthia that there's no formal allegation
24 process going on because you don't have a site? Is
25 that what you said, Cynthia?

1 MS. FLANNERY: Right.

2 DR. MILLER: What I can say, Dr. Diamond,
3 is that if an allegation is brought to the NRC
4 concerning safety practices or security practices or
5 lack thereof, we have a formal process that we take
6 through an allegation review board. Based upon the
7 disposition of that board, the issue is studied and
8 resolved and if it's determined that the allegation is
9 substantiated, the NRC takes appropriate action, but
10 to do so we have to have specific information. I can
11 say that generally, with regard to the actual licensee
12 that the allegation is being made against or the
13 individual, licensed individual that the allegation is
14 being made against.

15 MEMBER DIAMOND: So if I understand you
16 correctly, Charlie, because you don't have specific
17 information, there's no formal allegation and
18 investigation at this time?

19 DR. MILLER: If that information is
20 lacking, then we can't proceed any farther because we
21 don't have the necessary information that we would
22 need to pursue whether the allegation should be
23 substantiated.

24 MEMBER DIAMOND: I was very concerned by
25 some comments that Dr. Kondziolka made that there's a

1 center in which the radiation oncologist is allegedly
2 blocking the participation by the neurosurgeon which
3 I think we all agree is completely inappropriate.
4 There's no question about that.

5 Is this center that we're all concerned
6 about, is that the same center or is that a different
7 center?

8 MS. EMERICK: Different center.

9 MEMBER DIAMOND: Then certainly, in the
10 same vein, if you have a specific center in mind which
11 is doing this to the neurosurgeons, I certainly would
12 like to know about it. I'm sure the rest of the
13 committee would like to know about it as well. I
14 would assume that you probably don't want to share
15 that with us as well?

16 MS. EMERICK: I think in a public forum
17 and --

18 MEMBER NAG: Can you have them use the
19 mic? We are not able to hear some of the words.

20 CHAIRMAN MALMUD: Did you hear Dr.
21 Diamond's question?

22 DR. MILLER: We heard the question, not
23 the response.

24 CHAIRMAN MALMUD: Would you respond again,
25 please?

1 MS. EMERICK: Yes, this is a public forum.
2 I don't think it's appropriate.

3 CHAIRMAN MALMUD: Mr. Lieto?

4 MEMBER LIETO: I guess I don't understand.
5 You're saying this is a document that's been sent out
6 and is being distributed to the general public and Dr.
7 Diamond's wanted some clarification --

8 MS. EMERICK: I've only been asked one
9 question by the NRC about who was included in here on
10 one thing. And neither one of those is what Dr.
11 Diamond is talking about.

12 MEMBER DIAMOND: If I may, on issue 6 on
13 page 28 right now --

14 MEMBER WILLIAMSON: I'm sorry, which page,
15 Dr. Diamond?

16 MEMBER DIAMOND: Sorry, Jeff. Issue 6,
17 page 28.

18 CHAIRMAN MALMUD: Dr. Diamond, which page?

19 MEMBER DIAMOND: Twenty-eight.

20 CHAIRMAN MALMUD: Twenty-eight. Thank
21 you.

22 MEMBER DIAMOND: "IRSA is aware that a GSR
23 radiation oncologist serves on NRC's advisory
24 committee for the medical use of isotopes." Who would
25 that be?

1 MS. EMERICK: I'm not sure where you're
2 reading from. Oh.

3 MEMBER DIAMOND: I'm reading --

4 MS. EMERICK: You.

5 MEMBER DIAMOND: It's okay to say my name,
6 if you like.

7 MS. EMERICK: Well, it's not an allegation
8 against you.

9 MEMBER DIAMOND: It's okay to say my name.
10 "The GSR center where the advisor works has an older
11 model U GSR unit, IRSA is unaware as to whether this
12 advisor is familiar with the new model C GSR
13 differences and its automation and other technically-
14 related issues."

15 Of course, that's about me. In the
16 future, just as a --

17 MS. EMERICK: That's not about you. I
18 said I was not aware.

19 MEMBER DIAMOND: In the future, we are a
20 scientific and technical advisory panel. One could
21 reasonably construe this to be somewhat of a demeaning
22 and condescending remark and I would appreciate it if
23 you picked up the phone and just said Dr. Diamond, I
24 have a question for you.

25 MS. EMERICK: I did pick up the phone and

1 I did call you and I had your center give me a call
2 back to discuss specifically this letter. You became
3 very upset and cut the conversation short and said if
4 there's anything going on that the NRC will go out
5 after the people and that was it. There was no
6 further contact from you.

7 MEMBER DIAMOND: Be very careful about
8 making ad hominem attacks, okay? Do you know what I'm
9 saying?

10 MS. EMERICK: We're here for patient
11 safety.

12 MEMBER DIAMOND: We're here for patient
13 purpose --

14 MS. EMERICK: That's all.

15 MEMBER DIAMOND: And I'm just trying to
16 say there are polite and civil ways to have a
17 conversation and this is not it.

18 I'd also like to ask you on the final
19 sentence of that paragraph, "we are aware that the
20 radiation oncologist group at this site is looking to
21 purchase the GSR operations from the local hospital,
22 whether wholly or partially, when they upgrade the
23 unit."

24 And again, why in God's earth would you
25 include that sentence in this public document?

1 MS. EMERICK: Actually, it was included so
2 the members of this Committee would understand that
3 you bring extra information to the Committee and you
4 might understand the new ownership models and
5 licensing models that are going on and how those can
6 promote patient safety.

7 MEMBER DIAMOND: Thank you.

8 MS. EMERICK: That was why you were
9 called.

10 CHAIRMAN MALMUD: Any other questions?
11 Comment?

12 MR. SHEETZ: Is this microphone working?
13 Mike Sheetz, University of Pittsburgh.

14 I have some comments and questions with
15 respect to the physical presence requirements
16 currently and the NRC regulations for gamma knife
17 stereotactic radiosurgery.

18 As stated, there has been over 100,000
19 cumulative gamma knife treatments in the United States
20 since 1987. There have been 29 medical events or
21 misadministration depending on when they occurred,
22 reported to the NRC and it's available from their
23 website and different information.

24 Overall, this is a pretty good performance
25 record and one might ask what is the problem, but

1 again, we strive for perfection both from the ACMUI
2 and the NRC and medical uses of radioactive material
3 and radiation.

4 If we break down causes for these medical
5 events or misadministrations, one was due to
6 mechanical failure; eight were due to patient set-up
7 errors, where they set up the wrong stereotactic
8 coordinates. They used the wrong collimator helmet
9 and so forth. Twenty were due to incorrect input data
10 with respect to the dose treatment plan. Ten occurred
11 all at one site due to an incorrect calibration factor
12 for the source activity. And these involved choosing
13 the wrong plan for the patient, wrong coordinates,
14 wrong dose, error in input data from imaging system.

15 Except for the one mechanical failure, the
16 cost for these events were due to human error:
17 failure to pay attention to detail; failure to follow
18 established procedures; miscommunications, the same
19 that were found on the ACMUI subcommittee,
20 investigation of medical events on iodine-131.

21 None of these events would have likely
22 been detected or prevented once the patient treatment
23 had been initiated, no matter who was sitting at the
24 console or physically present, the medical physicist,
25 the radiation oncologist, even the neurosurgeon.

1 These errors were already set in motion and they would
2 not have been detected or prevented.

3 If you look at the problems that are
4 occurring with respect to gamma knife treatments,
5 during treatment process, both Elekta and IRSA report
6 hearing about once a week, particularly occurrences of
7 a treatment shot needing to be interrupted most likely
8 due to medical reasons with the patient, the patient
9 become anxious, the patient's blood pressure drops,
10 they become nauseous and so forth. So it requires
11 some type of medical intervention.

12 Mechanical failure is very rare reported
13 by Elekta. They report less than one per year for the
14 mechanical problem causing a patient, you know,
15 treatment intervention.

16 Second point is that for patient safety
17 issues it would seem most important to have someone or
18 more than one physician present during the gamma knife
19 treatment who can initiate medical care. With respect
20 to the medical physicist they are neither qualified
21 nor privileged to provide any of this medical care.
22 And I would contend that a neurosurgeon is equally
23 qualified as an radiation oncologist to provide any
24 medical care necessary during patient treatment when
25 an intervention would be necessary.

1 And with respect to responding to
2 mechanical failures where you have to go in and remove
3 the patient from the device, the emergency procedure
4 is fairly straight forward. You go in and you pull
5 the lever from the couch, the couch becomes extracted
6 and then you merely need to detach the patient frame
7 from the helmet. On the tritium system, you use the
8 long-handled allen wrench; on the APS you use the
9 tritium extraction tool. It's pretty straight
10 forward and the patient slides out.

11 Almost anyone who is trained in emergency
12 procedures can perform this function. So I ask the
13 question what is the event or set of circumstances
14 that the NRC foresees that requires the special skill
15 set of a medical physicist and a radiation oncologist
16 to be present during the treatment process? And I
17 would contend that it's most important to have someone
18 there to be able to intervene medically as that is the
19 most common occurrence of problems that occur and I
20 would also make the suggestion that maybe since most
21 misadministrations were due to treatment planning
22 errors, it would be more appropriate for the medical
23 physicist to be concentrating on dose treatment
24 planning and not monitoring the console of the
25 treatment which can take many minutes to hours.

1 Thank you very much.

2 CHAIRMAN MALMUD: Thank you. Dr. Howe?

3 DR. HOWE: I just wanted to clarify that
4 earlier on there was, I believe, a statement that said
5 that they hadn't seen -- the gamma knife surgery
6 misadministrations had not involved patient movement
7 and I'd like you to know that within the last six
8 months, we have had two medical events in which
9 patient movement either violent movement by the
10 patient or coughing has contributed to the z-bars
11 moving. That's not to say they are the only reason
12 the z-bars move, but they've contributed to a movement
13 of 7 centimeters and a quarter of an inch. So we are
14 beginning to see medical events that are resulting in
15 z-bar movements.

16 CHAIRMAN MALMUD: Thank you, Dr. Howe.

17 MR. WHITE: I'm Jerry White and I'm here
18 representing the AAPM, the American Association of
19 Physicists in Medicine.

20 I'd like to begin by doing a mom and apple
21 pie agreement and paying homage to the team approach.
22 I think that everyone is agreed, we are as well, that
23 this is the central characteristic of stereotactic
24 radiosurgery.

25 We support the team approach. We also

1 support the effort that's been going on probably for
2 the last decade to revise the Part 35 T & E
3 requirements and other portions of Part 35. This has
4 been a long process, carefully considered by a large
5 number of people and I urge the ACMUI to honor the
6 effort that we've seen in the past.

7 The IRSA document which is on paper has a
8 great many laudable assertions regarding quality of
9 care for patients undergoing stereotactic radiosurgery
10 and we certainly agree that patient quality of care is
11 of the utmost importance, but most of the issues
12 raised are related to medical staff, medical
13 credentialling, standards of practice issues that are
14 outside the mission of the NRC and we feel, we agree
15 with some of the previous comments that additional NRC
16 regulation in this area is probably not appropriate.

17 The IRSA document, as part of establishing
18 credibility, made the point that it was a global
19 description of the stereotactic radiosurgery process
20 and we believe that that was an error. There is
21 insufficient recognition of Linac-based SRS in the
22 document. Although we recognize the historic
23 contributions of the gamma knife procedure, I think
24 the primary method of delivering stereotactic
25 radiosurgery in the United States is Linac-based and

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1 I think deficiency in the document, adversely
2 influences the readers perception of objectivity in
3 the document.

4 The document also does not recognize
5 frameless stereotactic radiosurgery which is an
6 important portion of the technique.

7 I mentioned this about Linac radiosurgery
8 just to make the point that in most states there is
9 not a regulatory mechanism for ensuring the team
10 approach for Linac-based stereotactic radiosurgery, I
11 think we see universally, we certainly do in my
12 institution the team approach is held sacred. So it
13 may not be necessary to have regulatory support for
14 this.

15 The issues related to quality as a
16 function of facility ownership, I think, are
17 interesting. And if, in fact, that is a systemic
18 problem, I think it might be appropriate for the NRC
19 to look at that, but there's been no evidence that
20 ownership per se is a surrogate or could be a
21 surrogate for quality.

22 The document makes several erroneous
23 statements about the training and role of the medical
24 physicist in the SRS process. And we would offer the
25 offices of the AAPM to talk to the IRSA people to more

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1 carefully describe what it is we do, but I'd like to
2 thank the two presenters who gave oral testimony today
3 for many kind comments about the role of medical
4 physicists in the procedure.

5 The document makes a number of errors, I
6 think, in interpreting NRC regulatory positions and
7 NRC regulations and I'll also mention that -- by way
8 of a commercial -- that AAPM members are frequently
9 involved in regulatory issues for our clinical
10 colleagues and although we don't provide medical care,
11 we do provide regulatory care and we'd be happy to
12 talk to the IRSA people about the history and
13 philosophy of NRC regulations as well as some of the
14 details.

15 Lastly, I'd like to say a little bit about
16 the proposal in the slides to modify the definition of
17 authorized medical physicist. Certainly, much blood,
18 sweat and tears about the existing definition of the
19 new Part 35 and the proposal made in the slides was
20 inappropriate. It mentioned AAPM membership as a
21 qualification. AAPM is a professional society, not a
22 credentialing board. There are a number of errors
23 there. And we would anticipate that that -- no one
24 would actually pursue that suggestion.

25 Lastly, to say something about physical

1 presence, this is the second time I've said "lastly",
2 I apologize for that.

3 (Laughter.)

4 Physicists ought to be able to count the
5 last comment better. The physical presence is not
6 something with which one can predict the actual task
7 that we will do and prevent. The physicist is the
8 hardware guy, the software guy. We don't handle
9 seizures in people, but we handle seizures in
10 machines. And it's difficult to say a priori what it
11 is we will do universally to solve a problem.

12 The analogy we use in our practice is that
13 being a medical physicist is a lot like being a
14 parent. You may only need to spend an hour a day with
15 your child, but it doesn't come in a predictable
16 fashion. It's five minutes here and ten minutes
17 there. And it's the same way for stereotactic
18 radiosurgery.

19 I'm almost embarrassed to say that I do
20 stereotactic radiosurgery because I'm humbled by the
21 experience that the other speakers had brought. We do
22 Linac-based radiosurgery, half a dozen patients a
23 month, not very much and I can say that the physical
24 presence part is deadly boring to sit through that
25 entire process is a real snooze, except for the five

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1 or ten seconds where it looks like something isn't
2 going right and it's that time when you need the
3 physical presence. It's unpredictable and I don't
4 have experience with the gamma stereotactic
5 radiosurgery, but I believe the principle is the same.
6 You can't predict when you're going to need the
7 physicist there, so the physicist is there all the
8 time.

9 CHAIRMAN MALMUD: Thank you. Other
10 comments?

11 Dr. Raizner?

12 MEMBER RAIZNER: I would just make two
13 comments. One is that I certainly share the concern
14 that the IRSA document is very bothersome to read,
15 that there was some unsubstantiated innuendos. There
16 were some personal affront without names. To read it,
17 was a -- I think it's an example of what you don't
18 want to put in a document to convey a cause that you
19 feel strongly for.

20 That having been said I do want to say
21 that I was very and am very supportive of Dr.
22 Kondziolka's -- I hope I'm pronouncing it close enough
23 -- issues and I think that one of the things that we
24 as a committee will have to address in the ensuing
25 years is that there is an evolution in radiation

1 treatment and the evolution is that multiple
2 specialties will be involved and patients of these
3 multiple specialties will benefit from these
4 treatments. In the years past, it was principally a
5 cancer treatment, but we see that this is changing and
6 as technology changes, God knows what treatments
7 radiation will offer our patients.

8 And with that, we will have to think of
9 different paradigms for the authorized user and I
10 completely concur with Dr. Eggli's comment earlier
11 that what the NRC should define is the knowledge base,
12 the training, but not specifically the administration
13 of the training. And currently that's a hindrance in
14 Part 35, something 60, whatever, that it specifies
15 very reasonable times and training and clinical
16 experience, but it dictates that the training must be
17 given by a particular approving body.

18 I think we have to evolve away from that.
19 Knowledge base is important. Who delivers that
20 knowledge base is less important and as radiation
21 therapy becomes more broad-based, involves more people
22 and more specialists, it's something that we as a
23 committee, I think, will have to advise the NRC to
24 work towards.

25 Thank you.

1 CHAIRMAN MALMUD: Thank you, Dr. Raizner.
2 Dr. Nag? No.

3 Oh yes. Will you please introduce
4 yourself?

5 MR. RAGLAND: Randy Ragland, NRC Region 1.
6 I'm wondering if the basis behind our statements of
7 consideration is within hearing distance of normal
8 voice or physical presence. If that means if the
9 intent is really to mean at or near the console or to
10 suggest that you don't need to amplify the human voice
11 through like a walkie-talkie because you could
12 interpret it to say hearing distance of normal voice
13 meaning that you don't have to use any kind of
14 amplification so you could be far enough distance away
15 that you could communicate with your voice. So I'm
16 wondering what the basis is for that?

17 CHAIRMAN MALMUD: Are you asking for the
18 historical basis for it?

19 MR. RAGLAND: Yes.

20 CHAIRMAN MALMUD: Does anyone know what
21 the historical is for that statement?

22 I don't know either. I would assume
23 though that what the intent was, but I'll ask Mr.
24 Lieto.

25 MEMBER LIETO: Well, I think the first

1 time this came up was when the NRC issued requirements
2 on all licensees as a result of the HDR incident in
3 Pennsylvania. And it became an immediate license
4 condition on anybody that had an HDR and that was the
5 first time my recollection that that came up.

6 CHAIRMAN MALMUD: I would assume it's
7 without amplification, otherwise, we could be
8 communicating with our colleagues in California or
9 China.

10 MEMBER LIETO: That's correct.

11 CHAIRMAN MALMUD: In real time. Dr.
12 Williamson, did you have your hand up?

13 MEMBER WILLIAMSON: Well, I guess I would
14 like to make some sort of a summary statement, I guess
15 reflecting my own views. I think that the comments
16 we've heard here today go back to I think the
17 fundamental basis of which all these regulations are
18 made which is the medical policy statement in which
19 you know there was a division between what is the
20 practice of medicine and what is the purview of the
21 NRC and I had been thinking about analogies in
22 radiation therapy. There are urologists who are
23 necessary sometimes and get involved in prostate seed
24 implants. There are ophthalmic surgeons who in my
25 experience have been key and essential players in the

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1 placement of episcleral eye plaques for ocular
2 melanoma. There are GYN oncology surgeons that are
3 very critical in many institutions for the placement
4 of intercavity insertions for the treatment of
5 cervical and other malignancies. So there is really
6 a lot to think about. Potentially, what has been
7 suggested is a different paradigm than we have now for
8 regulating credentials for the use of electronically
9 generated x-rays in therapeutic types of treatments,
10 kind of a micro specialization. So it seems to me the
11 issue raised is very broad, actually, and not so
12 narrow as it's applied here, merely requires a great
13 deal of fundamental soul searching and considering the
14 history and basis of the regulations and where the
15 dividing line should go between what is regulated and
16 what should be left to the other regulatory and -- I
17 shouldn't say regulatory, but QA and compensatory
18 mechanisms of the medical marketplace.

19 CHAIRMAN MALMUD: Thank you, Dr.
20 Williamson. Dr. Larson?

21 DR. LARSON: I'd just like to offer a few
22 thoughts in response to Dr. Raizner's comments which
23 I don't disagree with by the way regarding the
24 evolution and participation and the future of various
25 specialists hard to predict.

1 Let me just offer the following to provide
2 some context, that historically focal treatments of
3 tumors whether surgical or with radiation therapy have
4 been treatments carried out by the appropriate
5 specialist, surgeon or radiation oncologist, and
6 historically, the surgeon or the radiation oncologist
7 needed clarification as to where the target was they
8 would consult with one of their colleagues in another
9 specialty. It might be radiology, thoracic radiology,
10 urologic radiology, neuroradiology. The surgeon might
11 consult before doing an operation with a radiation
12 oncologist to find out if a radiation oncologist might
13 have a way of taking care of something left behind and
14 vice versa.

15 Tools developed in all specialties
16 including surgery, as surgery develops. It may be in
17 the future that other specialists will be necessary to
18 participate. Tools are developing rapidly in
19 radiation oncology. It may be that as tools develop,
20 other specialists will be necessary. But it's not
21 clear if that's true and if that's in everybody's
22 interest or society's interest. So I just offer that
23 as perspective.

24 CHAIRMAN MALMUD: Thank you. Any other
25 comments or questions with regard to this subject?

1 If not, we'll move on to the next item on
2 the agenda which the administrative closing action
3 item review with Angela McIntosh.

4 MEMBER LIETO: Mr. Chairman?

5 CHAIRMAN MALMUD: Yes, Mr. Lieto.

6 MEMBER LIETO: I guess I'm trying to
7 understand on the issue that we were just closing up
8 on, on physical presence, were we being asked for a
9 recommendation to take this under consideration and
10 come back or are we just sort of like being informed
11 of an issue? I'm not real sure as to where we're
12 supposed to go with this next.

13 CHAIRMAN MALMUD: My impression is that
14 we've been informed and that we will discuss the
15 issue, but obviously, the way the program is
16 structured, it does not appear that it was intended
17 for us to discuss the issue to resolution today.

18 Do I interpret that correctly?

19 MR. ESSIG: Yes.

20 MEMBER LIETO: So this would be an issue
21 that would come back to to discuss or with the
22 recommendation, if appropriate?

23 CHAIRMAN MALMUD: Yes. I think that -- my
24 impression is and I'm happy to be advised and
25 corrected about it, is that we deal with these issues

1 one at a time as they arise because of the
2 evolutionary changes in the practice of medicine and
3 the advances in the science and therefore we deal with
4 one issue at a time. I think Dr. Williamson's
5 comments are very relevant in that there will be
6 significant issues to look at on a global basis. But
7 I assume that we are asked to deal with them one bit
8 at a time, to use someone else's terminology.

9 Small bites. Excuse me, Dr. Suleiman.

10 MEMBER SULEIMAN: I have a question. Just
11 because every issue gets brought to our attention, do
12 we have to -- can't we decide that we've gotten the
13 issue clarified and that it is what it is and then we
14 move on with some of the other issues?

15 CHAIRMAN MALMUD: I think that we owe the
16 parties involved a response and maybe even a
17 recommendation, but it would be premature for us to
18 come to that conclusion at this time, given the brief
19 time that we've had exposure to what they have shared
20 with us. We meet three times a year and we also have
21 conference calls available for subcommittees or
22 committees if we wish. And we can bring the issue
23 forward. This is not a pressing issue at the moment
24 that requires an immediate decision, is it?

25 MR. ESSIG: That's correct. And I think

1 what we'll do is review the totality of the meeting
2 minutes and decide whether or not we need to seek or
3 seek some advice from the committee.

4 CHAIRMAN MALMUD: Thank you. Was there a
5 comment you wish to make?

6 MR. SHEETZ: Yes, Mike Sheetz, University
7 of Pittsburgh again. I do want to make a comment and
8 maybe direct a more specific question to the
9 committee. We have twice submitted for an amendment
10 request for an exemption to the physical presence
11 requirement to allow one of our qualified
12 neurosurgeons to be able to substitute for the
13 radiation oncologist, after the initiation of the
14 treatment, to be physically present so the oncologist
15 could leave the area. This was refused both times.

16 We submitted a third request and because
17 we have multiple units, part of the justification was
18 that we may have more than one treatment going on at
19 the same time and the Commission responded back
20 approving it, but with several conditions. There had
21 to be at least two treatments going on at one time.
22 At each console must be a neurosurgeon and then the
23 radiation oncologist could float back and forth which
24 really didn't gain us any ground. It didn't relieve
25 the oncologist to do other things or be involved in

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1 dose treatment planning and so forth.

2 So I guess the specific question I have to
3 the committee is and I think this has been posed
4 previously, can we make a generic, this may be
5 proposed rulemaking, but -- or can you make general
6 guidance that a qualified neurosurgeon with the
7 appropriate training in gamma knife procedures and
8 emergency procedures substitute for the radiation
9 oncologist for the current physical presence
10 requirement? Is that an appropriate exemption and/or
11 maybe an initiation for proposed rule -- maybe the
12 response would be no, that has to be proposed
13 rulemaking and that would be the process. So I'm
14 looking for guidance on that.

15 Thank you very much.

16 CHAIRMAN MALMUD: Dr. Diamond?

17 MEMBER DIAMOND: Mr. Sheetz, I guess I'm
18 a little confused. My understanding was and I forget,
19 this was about two years ago or so now, that the
20 request was to obviate the need for a radiation
21 oncologist to be at each of the consoles because of
22 patient needs elsewhere and I thought that the ACMUI
23 gave you a response which is exactly what you wanted.
24 I remember having that discussion. I thought the
25 specific request was to go and lessen the burden and

1 I seem to remember that's exactly what we intended to
2 give you.

3 DR. WALLNER: Mr. Chairman, if I could
4 make a comment.

5 CHAIRMAN MALMUD: Dr. Wallner.

6 DR. WALLNER: My understanding is that the
7 initial request for the exemption for the University
8 of Pittsburgh was based on their premise that
9 radiation oncologists were not available or not
10 interested in being available. I believe the
11 Committee has in front of it a letter from Dr.
12 Flickinger and Dr. Greenberger from the University of
13 Pittsburgh that completely disavows the Department of
14 Radiation Oncology of that position. That is not the
15 position of the Department of Radiation Oncology at
16 the University of Pittsburgh. The authorized user
17 must be present.

18 CHAIRMAN MALMUD: Dr. Miller?

19 DR. MILLER: Getting back to the previous
20 question of is there any action today that the
21 Committee needs to take, leave two things on the
22 table. One, there are many issues that the staff asks
23 the Committee to undertake to advise us. But there is
24 nothing in the by-laws that it's intended, I think,
25 that if the Committee ever sees issues that they that

1 they need to advise the staff on or make
2 recommendations to the staff on, from your own
3 expertise, that need addition with regard to issues
4 that are under NRC's purview, you're free to do so.

5 So based upon the information that you
6 heard today, if you chose to do that, you would be
7 within your rights. You would not have to have the
8 staff do that. I'm not asking that you do that, I'm
9 just offering that there's two ways that issues that
10 are brought before the Committee can be pursued.

11 MEMBER NAG: Who is the NRC staff on this
12 issue? Who is the assigned NRC staff?

13 DR. MILLER: They would be members of my
14 staff --

15 MEMBER NAG: I know that. Anyone specific
16 who had been assigned this task?

17 DR. MILLER: I'd have to -- Tom, do you
18 know?

19 MR. ESSIG: Assigned the task of --

20 MEMBER NAG: You know, the physical
21 presence in gamma knife and that issue.

22 MR. ESSIG: We have a couple of staff that
23 are certainly knowledgeable, and Dr. Howe and Dr.
24 Zelac --

25 MEMBER NAG: No one person? You know we

1 had the expert for the medical events, we had someone
2 to talk to.

3 DR. MILLER: Dr. Nag, I think your
4 question is does the NRC have any staff members
5 assigned to studying the issue with regard to making
6 a recommendation.

7 We received various letters as has been
8 brought forward to the Committee today and staff
9 evaluates that information and decides if we need to
10 take any action or we need to engage the Committee on
11 making any action.

12 But as I said before, based upon the
13 evidence that was put before you today, the Committee
14 is free to make a motion and pass a motion to
15 undertake such an activity, if you see fit to do so.

16 MEMBER DIAMOND: This is Dr. Diamond
17 again. So Charlie, when I was listening to Dr.
18 Kondziolka, many of his comments related to quality
19 assurance issues, particularly at non-hospital based
20 centers in which there's a concern that the oversight
21 and that the patterns of care may not be optimal and
22 that's a real issue.

23 Now a strict interpretation of our mission
24 statement would say that some of these issues were
25 outside of our purview, but if I understand you

1 correctly, perhaps there's some wiggle room, for
2 example, to make recommendations regarding that the
3 Advisory Committee believes that it is inappropriate
4 to exclude a neurosurgeon, be present as part of the
5 procedure. Are you saying things like that can be
6 integrated? Because I think we all agree in unanimity
7 that it essential for the neurosurgeon to be there as
8 well. In any situation where that's not occurring,
9 must cease. And the question is how can that be done?

10 So again, is there any methodology that
11 without violating our charter, we can go and make
12 progress on that issue?

13 And again, it's kind of difficult now that
14 it's already 4:20 and some of us have planes to catch,
15 but --

16 DR. MILLER: I guess my reaction is I
17 think there is as long as we stay within NRC's
18 regulatory responsibilities and we don't encroach on
19 the practice of medicine. Then I think that would be
20 outside this Committee's functions. I don't know if
21 that answers your question, Dr. Diamond.

22 MEMBER DIAMOND: I don't think we ever
23 considered this before, so it's something to think
24 about.

25 CHAIRMAN MALMUD: May I take us back a

1 step? The current standards require the authorized
2 user be present for the entire procedure. That
3 authorized user may be a radiation physicist, a
4 radiation oncologist -- who is the authorized user?
5 The radiation oncologist. And is there any other
6 authorized user, in general terms? There are specific
7 exceptions, are there not? Or is it always a
8 radiation oncologist?

9 DR. MILLER: Always radiation oncologist.

10 CHAIRMAN MALMUD: Always radiation
11 oncologist. And then we have a letter dated April 6th
12 from Drs. Herrod, Greenberger and Flickinger which
13 says that due to a misunderstanding we were given to
14 believe that they were supportive of not having to
15 have the proposal that was put before us earlier and
16 in fact, they are not supportive of that proposal.

17 And in fact, it says "for the record, the
18 University of Pittsburgh has adequate physician and
19 physicist staffing levels within the Department of
20 Radiation Oncology and follows all NRC regulations
21 including fulfilling the physical presence
22 requirements for radiation oncologists during gamma
23 stereotactic radiosurgery."

24 So we do agree that that is a standard
25 that we're not budging from at the moment? Or are

1 there exceptions to that standard anywhere in the
2 United States?

3 MR. RAGLAND: I believe there are several
4 facilities that have an exemption where an authorized
5 user, where a neurosurgeon could substitute for an
6 authorized user as long as it went for more than 50
7 percent of the treatment and the authorized user was
8 immediately available.

9 CHAIRMAN MALMUD: Dr. Howe?

10 DR. HOWE: We granted an exemption to one
11 licensee, that they had to start the procedure with
12 the authorized user and the authorized medical
13 physicist and the authorized user had to be physically
14 present for 50 percent of the treatment.

15 CHAIRMAN MALMUD: May I ask why the
16 exemption was granted?

17 DR. HOWE: I believe the licensee stated
18 medical care for other patients as part of the reason
19 that the authorized user may be called away to
20 participate in patient treatment, but it wasn't
21 supposed to happen all the time and they guaranteed
22 that the authorized user would be there at least 50
23 percent of the time so that for very long procedures,
24 the authorized user could be called away in need of
25 emergency.

1 MEMBER DIAMOND: Kansas City?

2 DR. HOWE: Kansas City would not be an NRC
3 licensee. I think it's in Region 1. Region 3.

4 CHAIRMAN MALMUD: Dr. Vetter.

5 DR. HOWE: And we also granted an
6 exemption to Pittsburgh for multiple uses.

7 MEMBER VETTER: In the case of that
8 exemption, is the neurosurgeon present?

9

10 DR. HOWE: Yes.

11 CHAIRMAN MALMUD: So there's an exemption
12 in which the neurosurgeon can be present and the
13 radiation oncologist absent for 50 percent of the
14 time?

15 DR. HOWE: Yes, because the neurosurgeon
16 would be considered to be the medical person there
17 that would respond to medical emergencies.

18 CHAIRMAN MALMUD: Is that neurosurgeon
19 declared an authorized user?

20 DR. HOWE: No.

21 CHAIRMAN MALMUD: No.

22 DR. HOWE: The neurosurgeon has never been
23 an authorized user. They may have had an authorized
24 neurosurgeon, but not an authorized user.

25 CHAIRMAN MALMUD: And did someone mention

1 there was a second exemption?

2 DR. HOWE: We granted a second exemption
3 to the University of Pittsburgh for multiple units
4 being used at the same time and in that case we
5 allowed the neurosurgeon to take the place of the
6 authorized user at one of the sites, but the idea was
7 that the authorized user had to be physically present
8 at the other unit so that they could be called to the
9 -- if there was an emergency at the second unit, they
10 could respond and there would still be a neurosurgeon
11 there and there would still be an authorized medical
12 physicist.

13 CHAIRMAN MALMUD: So they would float
14 between two units in the same building?

15 DR. HOWE: They were in the same suite.
16 The suite is very large, so you need to get that
17 concept. The gamma knife units are about 100 feet
18 apart.

19 CHAIRMAN MALMUD: Thank you. Dr. Miller,
20 did you want to give us any other advice?

21 DR. MILLER: Take two and go to the right.
22 I think that the issue is twofold. One I have to ask
23 myself to evaluate it more and decide if there was an
24 issue that requires any kind of action on the part of
25 NRC. But as I said earlier, I'm not asking you to do

1 so, but if the Committee is a body of wisdom, medical
2 wisdom, feels that based upon what you've heard today,
3 there's an issue where you think NRC needs to take
4 some kind of regulatory action or further evaluation,
5 you're free to provide, as a body, that advice that we
6 should take that on.

7 I'm not in a position today to say one way
8 or another. I would need personally I would need
9 further evaluation from staff before I would make such
10 a statement.

11 CHAIRMAN MALMUD: Dr. Williamson? I was
12 going to ask if the members of the Committee felt that
13 they wish to make a decision at that time or have
14 additional opportunity to discuss this amongst
15 ourselves?

16 I've given you two options. Does the
17 Committee feel that it would want to vote on this
18 issue now?

19 Dr. Williamson?

20 MEMBER WILLIAMSON: I really think the
21 underlying issue is not a small bite. I think it's a
22 major philosophical issue that drives at the very
23 heart of the regulatory system and involves
24 fundamental discussion about where the boundary is
25 between the scope of NRC's regulatory activity and

1 what is practice of medicine. I don't think it's a
2 simple yes or no kind of thing. I certainly feel
3 uncomfortable about dealing with it under these
4 circumstances and I think it would be a major effort
5 of this Committee to take on this without a strong
6 regulatory need being established. That would be my
7 observation. I think we would have a very limited
8 chance of success.

9 CHAIRMAN MALMUD: Dr. Suleiman?

10 MEMBER SULEIMAN: Well, I thought
11 yesterday we heard that the caregiver filed for an
12 exemption, see if we get lots of exemptions and then
13 propose possibly rulemaking changes in the future if
14 appropriate.

15 I now hear that we've got one situation
16 where there has been an exemption granted. It sounds
17 to me like there's a process already in play and
18 there's a way to address these issues and let's just
19 let things -- if more institutions want to file for
20 that exemption since the precedent seems to have been
21 set at least once, if you get a flood of these across
22 the country or whatever, maybe there's a need to
23 address this further. Or, if this is an isolated
24 case, then we can just let things work out rather than
25 discussing it here.

1 CHAIRMAN MALMUD: I must say that I remain
2 puzzled as to why Pittsburgh is asking for an
3 exemption when the radiation oncologists at Pittsburgh
4 say there is not a need for one.

5 DR. KONDZIOLKA: Can I address that, Dr.
6 Malmud?

7 CHAIRMAN MALMUD: Yes, please.

8 DR. KONDZIOLKA: I was going to remain
9 quiet on that letter, but since you brought it up, I'd
10 like to address your puzzled aspect of it.

11 I, too, was very puzzled by it. I was
12 made aware of this letter at quarter to 1 this
13 afternoon and I think the key person who signed that
14 letter is Dr. Flickinger and since it will go into the
15 record here, I'll say about one minute on this.

16 I spend 90 percent of my work week with
17 John Flickinger who is a superb and brilliant
18 radiation oncologist and close personal friend. I
19 also say I've had lunch with already two times this
20 week and he never brought that letter to my attention.
21 Not once since it was apparently signed on April 6th.
22 So I phoned him up at a quarter to one this afternoon
23 before I came in this room and I said, "John, what's
24 with this letter?" I said I agree with the first
25 paragraph. I agree with the second paragraph. In

1 paragraph three, what exactly is the issue that you
2 are objecting to, because there's a number of issues
3 because the letter specifically doesn't say that. And
4 the issue was the physical presence of the radiation
5 oncologist. I said well, John, what we've been
6 talking about is the ability for you to walk across
7 the hall to do a consult and come back in 10 minutes
8 and right now you are not allowed to do that. And
9 don't you want to be able to do that and I sit there
10 monitoring our patient for the 10 minutes. That's
11 what we're talking about here, not breaking up the
12 team, not changing patient quality.

13 He says well, this letter came from the
14 standpoint that ASTRO leaned on the Department on
15 Radiation Oncology to make a comment and as John said,
16 I was forced to sign it. Now he did sign it and it's
17 in the record and that's fine and if he truly believed
18 that this was not in his best interests or the
19 Department's, he shouldn't have signed it, but he did
20 and so that's why I was not even going to comment on
21 it, but that is the genesis of it. I also want to say
22 that Dr. Wallner mentioned what with the University of
23 Pittsburgh standing, it's not the University of
24 Pittsburgh standing, but it is the official Department
25 of Radiation Oncology standing. It's not the

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1 Department of Neurosurgery, nor have you heard it from
2 the Radiation Safety Officer at the University of
3 Pittsburgh either.

4 CHAIRMAN MALMUD: Thank you. The letter
5 is signed by the Chairman of the Department of
6 Radiation Oncology at Pittsburgh who I assume outranks
7 the professor. And that's Dr. Greenberger and also
8 the Vice Chairman for Clinical Services, Dr. Herrod.
9 So the letter is signed by the three. Is that the
10 size of the department, three men?

11 DR. KONDZIOLKA: You're correct, it's a
12 large department and the other two are the clinical
13 and academic leaders of the department.

14 CHAIRMAN MALMUD: Mr. Lieto?

15 MEMBER LIETO: It still, I think supports
16 what you just said is that the testimony that was just
17 given, there's not a problem with adequate physician
18 physicist staffing. I think we just heard here that
19 they agreed with the first two paragraphs, so again,
20 I think it gets back to the point that was brought up
21 earlier is why the exemption for Pittsburgh. They
22 have adequate physician and physicist staffing to meet
23 the current regulations.

24 And my second point is that I think we
25 should -- we might want to table this until we get

1 some further input and so forth because I believe it's
2 a requirement, Part 35, that an authorized medical
3 physicist is present for these procedures, so if
4 you're going to try to establish a generic exemption,
5 basically what you're doing is requiring a change in
6 rulemaking because you can't exempt all medical -- the
7 requirement for all medical physicists being present.

8 CHAIRMAN MALMUD: Dr. Miller and then Dr.
9 Nag.

10 DR. MILLER: I agree one hundred percent
11 with what Mr. Lieto just said.

12 CHAIRMAN MALMUD: Thank you.

13 MEMBER NAG: I remember the discussion in
14 ACMUI. I'm not sure exactly when. I don't have my
15 notes, but the ACMUI had felt that if in this
16 particular situation where there are two machines
17 right next to each other and one person is right there
18 who is basically within hearing distance of both, that
19 person could serve to oversee both. I mean this is
20 quite opposed to any other place where you have one
21 machine and someone asks not to be in that machine at
22 all.

23 Here, you have two machines and one person
24 could oversee, one radiation oncologist could oversee
25 both of them and one neurosurgeon at the other machine

1 and I remember that discussion quite well and we felt
2 that was reasonable and I know I voted yes.

3 CHAIRMAN MALMUD: Thank you. I must tell
4 you that I won't make the decision, the Committee
5 will, but I, as chair, am still troubled by this
6 because there are two exemptions that I do not fully
7 understand and I do understand this request which is
8 essentially very similar to having a staff
9 anesthesiologist float between two rooms with a nurse
10 anesthetist doing anesthesia because the two rooms are
11 adjacent to each other and the staff anesthesiologist
12 could not do both rooms at one time and if that's what
13 this is analogous to, I can understand that we can
14 discuss that and perhaps accept that. But I would
15 still like to see the basis of the other two
16 exemptions so we can bring the whole thing to a full
17 discussion and then make a wise decision, carefully
18 first discussed with the facts at hand. I don't feel
19 in that position at the moment.

20 My question is do any of you feel
21 comfortable with this at the moment and wish to move
22 on it?

23 Dr. Diamond?

24 MEMBER DIAMOND: Since I'm the one that
25 actually wrote the ACMUI note in support of the

1 application, I unfortunately, as I get older, can't
2 remember all the details from two years ago, but I
3 would be happy to go through my records at my office
4 and distribute that letter to everyone. As I seem to
5 recall, the tenor of the request was was the premiere
6 center of the country doing this or adding a third
7 unit. This unit is physically very close to the other
8 two units. All the members of the treatment team
9 being the authorized user, neurosurgeon, the physicist
10 are all in agreement that this is a useful and
11 reasonable exemption request and based upon that
12 tenor, as I recall, the entirety of this Committee,
13 felt that that was reasonable.

14 Now again, I can't remember the details,
15 but I do have the letter at my office and I'd be happy
16 to circulate it.

17 CHAIRMAN MALMUD: And I would love to see
18 it, because I think we need more data in front of us
19 so we can make the correct decision and serve all
20 parties well.

21 I have no preconception about what the
22 outcome would be.

23 Dr. Williamson?

24 MEMBER WILLIAMSON: I would make a motion
25 that our mid-meeting conference call we ask, one of

1 the staff be asked to review the history of these
2 license amendments at the University of Pittsburgh and
3 previous ACMUI motions on the matter so that we could
4 determine whether there is any decision or proposal to
5 be made and I would then as a second part of my motion
6 propose we table this discussion for now pending that
7 review.

8 CHAIRMAN MALMUD: Is there a second to Dr.
9 Williamson's motion?

10 (Second.)

11 CHAIRMAN MALMUD: All in favor?

12 (Ayes.)

13 Any opposed?

14 (No response.)

15 Any abstentions?

16 (No response.)

17 The motion carries. We will bring this to
18 our next meeting, whether it be a publicized
19 conference call or this meeting and with more facts at
20 our fingertips.

21 Thank you very much, and also appreciation
22 to each of our guests who presented varying positions
23 on this issue today. You each expressed your
24 interests and concerns very eloquently and given us a
25 lot to think about and we're trying to come to a

1 conclusion as soon as possible.

2 If we may then move on to the next agenda
3 item which is that of Angela McIntosh.

4 MS. McINTOSH: Thank you, Dr. Malmud. The
5 purpose of my discussion is just to go over -- to sort
6 of summarize what was discussed today and to give a
7 very rough overview of some of the action items and
8 recommendations. I'm working from raw notes so I'm
9 not going to be able to give you -- I'm not going to
10 be able to cover everything and give you a thorough
11 overview because our scribe, although she does a
12 fantastic job, she's not -- it's not a word for word
13 capturing of what occurred here at the meeting.
14 That's the purview of the court reporter, and of
15 course, that transcript is not going to be back for
16 several days, so if there's something that anyone
17 remembers, then just feel free to speak up and say oh
18 yes, we agreed to this or we agreed to that.

19 What I'm going to start off with is just
20 very quickly going over what was recommended and the
21 action from the October 2004 meeting and some of the
22 action items that were agreed upon at that meeting and
23 give you a status update of that and then move on to
24 what occurred at this meeting.

25 There were several action items and

1 recommendations made at the October 2004 meeting. The
2 first one on my list was a recommendation made in
3 association with the agenda topic radioimmunotherapy
4 and microsphere therapy. What happened though during
5 the course of discussion somehow discussion shifted to
6 the C-Solectron permanent implant device so no actual
7 recommendation was made in association with the agenda
8 topic.

9 In association with -- well, the
10 recommendation that came from the discussion of the C-
11 Solectron permanent implant remote afterloader device
12 was that the NRC staff continued to regulate permanent
13 prostate brachytherapy in 10 CFR 351000, but used
14 35400 as the regulatory framework for creating
15 guidance while adding elements of 35600 as necessary.

16 MEMBER NAG: I think you -- it should be
17 not permanent prostate brachytherapy but permanent
18 afterloader because permanent prostate brachytherapy
19 like when the prostate brachytherapy review. Here we
20 are talking about the nucleotron's first afterloader
21 permanent prostate brachytherapy. Otherwise, it's
22 not. Really, permanent prostate brachytherapy is under
23 35600.

24 MEMBER WILLIAMSON: I agree with Dr. Nag.
25 The way it reads here is all permanent prostate

1 brachytherapy, regardless of whether it uses a
2 computer-assisted device or not, should be continued
3 to be regulated by 351000 which is absolutely false.
4 It is not now nor ever has been regulated by 1000.
5 It's only this very special niche in permanent
6 implants, so I think it needs to be clarified that
7 permanent implant via robotic seed insertion
8 mechanisms continue to be.

9 MEMBER NAG: I think the permanent
10 afterloader --

11 MEMBER WILLIAMSON: Yes.

12 MEMBER NAG: The word afterloader should
13 be somewhere in there.

14 Permanent prostate brachytherapy by
15 afterloader.

16 MS. McINTOSH: By afterloader?

17 MEMBER NAG: Something like that. It's
18 not all prostate brachytherapy.

19 MS. McINTOSH: Okay.

20 MEMBER NAG: Brachytherapy is 99.9 percent
21 of all prostate brachytherapy is done by the -- under
22 35400. There's only one special kind of prostate
23 brachytherapy by a new machine that we are referring
24 to here.

25 MS. McINTOSH: Okay, we can adjust that

1 wording, but the response that we gave to that
2 recommendation was that we agreed with ACMUI's
3 approach with aligning the guidance for the C-
4 Selectron closer to the requirement and 35400 and 600,
5 but the guidance, the development of it was on hold
6 because of a lack of a licensing request for this
7 particular modality.

8 MEMBER WILLIAMSON: I think when it gets
9 ready to move again, it would be prudent to
10 reconstitute the New Technology Subcommittee or
11 whatever we called it to look at that because there
12 was a strong concern that the proposed licensing
13 guidance was incredibly complicated and much more
14 restrictive in the practice of manual brachytherapy
15 and it went beyond the scope of that instrument.

16 MS. McINTOSH: Thank you. The second
17 recommendation on the list has to do with the NRC
18 staff asking the ACMUI for advice on creating any
19 guidance in association with the use of iodine seeds
20 as markers in breast cancer tumors and as everyone
21 knows we really couldn't move forward with that at
22 this meeting because we feel that a key player, a key
23 resource, Robert Gallagher, was not able to be here at
24 this meeting, so our move forward is to schedule a
25 teleconference sometime between now and the fall

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1 meeting or we could always adjust that and rediscuss
2 it at the fall meeting, but in any case, to move on it
3 at the earliest in a teleconference between now and
4 the fall meeting.

5 MEMBER VETTER: Before that conference
6 call, could you make it very clear what it is that
7 you're seeking from ACMUI, in the notice of the
8 conference call?

9 MS. McINTOSH: Yes. The next
10 recommendation on the list, actually about the next
11 three recommendations on the list were made in
12 association with the rule that is now final and so our
13 basic response to the recommendations on page 3 and
14 the recommendation 200505R on page 4 was that we will
15 consider action -- we will process this action in
16 accordance with how we process all comments during the
17 comment period of any rule. And so the final rule is
18 out and the Commission has made a determination on
19 those action items, so really the answer to those
20 items are contained in the final rule.

21 The next item on the list, the next
22 recommendation, proposed change to the abnormal
23 occurrence criteria, the ACMUI recommended that we
24 express dose and rem rather than rad in response to
25 the proposed criteria that we presented to you and

1 that we move to use the term the capture of events
2 that involve the medical administration of by-product
3 material.

4 Staff, after considering the ACMUI's
5 recommendation, believed that it's best to leave the
6 expression of dose in terms of absorbed dose rad
7 rather than rem. We just took a look at the kinds of
8 therapies, anticipated therapies in the future and we
9 just felt that rad was an overall better term to use.

10 MEMBER NAG: Which page is this?

11 MS. McINTOSH: This is page 4. And
12 regarding the ACMUI's recommendation that we require
13 the reporting of events involving the medical
14 administration of material, we also felt that it was
15 better to keep the existing language that requires
16 reporting of medical events because in order for an
17 event to be an OA, it has to be a medical event first.
18 So we just felt it was better that we not change that.

19 Starting with page five, there was a
20 recommendation that the ACMUI made in response to Dr.
21 Vetter's presentation on the ICRP recommendations and
22 the ACMUI recommended that the ICRP maintain the 500
23 millirem dose limit to pregnant workers and Dr. Vetter
24 took that recommendation to the ICRP meeting on
25 October 19.

1 I'm sorry, I misspoke. The Advisory
2 Committee on Nuclear Waste was hosting this meeting
3 and Dr. Vetter took your recommendation to the
4 Advisory Committee on Nuclear Waste. Thank you.

5 The next item on the list is an action
6 item, a request for ANP status that was forwarded to
7 us from Newark Beth Israel Hospital. The ACMUI really
8 did not have much to say about that. The ACMUI
9 reviewed the application and recommended that staff
10 not grant status to the individual and we agreed.

11 The next item on the list concerning dose
12 reconstruction, a Dr. Sherbini, Sami Sherbini gave a
13 presentation on the staff's response to -- he gave a
14 presentation finalizing our reaction to the dose
15 reconstruction effort that the Commission gave us an
16 assignment to respond to and it was made mention in
17 the meeting that the ACMUI had not seen the actual
18 hard copy response and that was requested at that
19 meeting and we did supply the ACMUI with a copy of our
20 conclusion. So that item was closed out at the
21 meeting.

22 The next item on the list is another, next
23 two items are action items. The top one, medical
24 event review of iodine events. We got some feedback
25 from the ACMUI on that. We asked the ACMUI to review

1 the medical events involving radioiodine or medical
2 events and of course, the subcommittee met, came back
3 and gave us several recommendations which Dr. Eggli
4 presented to us today, so we simply have -- we have
5 that information now. You've already forwarded that
6 to us and I believe -- I remember there being a
7 specific recommendation regarding dose calibrators
8 made in some capacity, but in any case, all of your
9 recommendations are contained within Dr. Eggli's
10 presentation, so staff has the answer to that request.

11 The next item on the list, this item, I
12 believe the staff, it was made specific to Mr. Lieto
13 and I believe we just basically backed off of this
14 one. It says that Mr. Lieto would search the NRC's
15 Nuclear Events Database and help frame the response
16 regarding medical events and what to do to reduce
17 them.

18 We've got the response, basically, so I
19 don't believe that specific action was carried out or
20 was it?

21 MEMBER LIETO: I think it was in relation
22 to the I-131 medical event, but in reading this, I'm
23 getting the impression that the intent may be that
24 you're requesting an on-going like maybe annual review
25 and submission to the ACMUI? Or is that something you

1 want to talk about?

2 MS. McINTOSH: That's something we can
3 talk about. I remember from the last meeting sort of
4 I think he volunteered to do that. I don't think that
5 we specifically asked you to do that.

6 MEMBER LIETO: Dr. Vetter?

7 MEMBER VETTER: I could be in error. My
8 recollection was that the subcommittee was appointed
9 to look at I-131 and Ralph asked a question about what
10 about other events and he basically volunteered or got
11 volunteered to look at other events other than I-131.

12 And I think it was just a one time thing.

13 MS. McINTOSH: Right, okay, I do recall
14 that. And then we came back and actually said well,
15 we have other personnel at NRC that -- I remember you
16 stating what about transportation events or something
17 like that and we came back and said well, actually, we
18 have other personnel at NRC that looks at that. So we
19 don't really need to go in that direction. So I think
20 this is kind of a -- it wound up being a no never mind
21 kind of item.

22 MR. ESSIG: Let me just clarify one point
23 that is that we have a continuing need from the
24 Committee to assist us in the review of events to
25 identify generic issues. That's a very valuable input

1 by the Committee. And I think the point that was made
2 yesterday was that if we strictly give you just the
3 NMED summaries, that the data in there are
4 insufficient and although the references are listed
5 sometimes getting into Adams and other ways is maybe
6 not the most efficient use of members' time. And I
7 think we agreed yesterday to take an action that when
8 tasked you to do that, we material we provide to you
9 when we do that review will give you the background
10 documentation beyond that paragraph summary that is in
11 NMED to facilitate the review.

12 MS. McINTOSH: The next action item on the
13 list has to do with another item that was discussed
14 today and not finalized, but it addresses this. The
15 ACMUI subcommittee was to hold some teleconferences to
16 discuss updating the medical event criteria definition
17 and that was done on a couple of occasions. And as a
18 result of that we have the subcommittee's report that
19 the ACMUI voted on and so the staff will have that
20 information to process once we get the transcript back
21 and we can address it more specifically. But a couple
22 of action items that came out of that, I believe Dr.
23 Nag is to e-mail some slides to the entire Committee.

24 MEMBER NAG: Yes.

25 MS. McINTOSH: And then the ACMUI will

1 consult with professional societies regarding an
2 attempt to address egregious behavior on the part of
3 some practitioners who might do something outside the
4 intent of the regulations. I believe an action item
5 was that the ACMUI will consult with professional
6 societies to see if they can help address some
7 language that will sort of minimize egregious
8 behavior, something to that effect.

9 MEMBER WILLIAMSON: I don't think that was
10 the -- we basically voted on two of three of the less
11 controversial points that were in the report and
12 approved them. I think that the bottom line is just
13 the work is unfinished and we need to keep meeting to
14 do that. We have some ideas on how to proceed that
15 we're going to sit down and go back at it and try to
16 express our concepts more in ordinary language and
17 leave it to you, the experts, to translate them into
18 rule language and then come back. I think that will
19 help facilitate the communication among us in the
20 agreement.

21 My impression is that this is not ready to
22 be closed out and that I suppose we could ask the
23 Chairman if it would be appropriate for us to continue
24 our efforts meeting via a conference call, perhaps
25 with some additional consultants to help us.

1 CHAIRMAN MALMUD: That's a recommendation,
2 the Chairman accepts the recommendation.

3 MEMBER WILLIAMSON: And we continue and
4 try to have a report available with better defined and
5 less controversy within the subcommittee as we -- at
6 least conceptual definition of what medical events
7 should be.

8 MS. McINTOSH: Okay, if that's no longer
9 an action item of the Committee, I can certainly cross
10 that out.

11 The last action item that I recall in
12 association with this topic is the ACMUI believes it
13 may be worthwhile for the NRC staff to explore
14 creating some sort of generic communication to define
15 what the end of the procedure is.

16 MEMBER WILLIAMSON: That I believe was not
17 approved.

18 MS. McINTOSH: This is an action item.
19 These are not recommendations.

20 MEMBER WILLIAMSON: Okay.

21 MS. McINTOSH: The one that I just named,
22 about going to professional societies, that was also
23 an action item. It wasn't a recommendation that was
24 voted on.

25 Am I correct there?

1 MEMBER WILLIAMSON: What's the difference
2 between an action item and a recommendation that's
3 voted on?

4 MS. McINTOSH: A recommendation, you are
5 formally giving us advice on something and asking us
6 to go forward and give you a response on that advice.

7 An action item is just a task that's being
8 agreed upon. There's no formal, legal implications
9 associated with an action item.

10 MEMBER WILLIAMSON: Okay, I stand
11 corrected. I was thinking action item is something we
12 had voted on and achieved consensus on.

13 MS. McINTOSH: Can I then take that to
14 mean that the previous action item that I stated with
15 regard to consulting professional societies is that
16 still an action item of the Committee?

17 MEMBER VETTER: I don't think we agreed to
18 formally consult with societies, did we? We agreed to
19 consult with colleagues in other societies, so we
20 would be doing that more or less on an informal basis.

21 MS. McINTOSH: So it may be better to
22 restructure this to say the ACMUI will simply consult
23 with colleagues. Okay.

24 MEMBER NAG: I don't know whether this was
25 an action item or not, but we had asked to have the

1 meetings or at least the dates agreed upon well in
2 advance like six months to a year. I don't know
3 whether it's a formal recommendation or action item or
4 what, if it is not, I'd like to make that an action
5 item.

6 MS. McINTOSH: Can you repeat that,
7 please?

8 MEMBER NAG: The NRC Staff require well in
9 advance, in parenthesis, six months to one year, the
10 dates for future NRC meetings.

11 MS. McINTOSH: Okay. That's actually the
12 next thing on the list. We always at the conclusion
13 of every meeting try to at least establish the meeting
14 date for the next meeting. It may be -- it's very
15 difficult to go out beyond the next meeting date
16 because we never know. It's just difficult. We don't
17 know -- it's difficult to project much further out
18 than six months.

19 MEMBER NAG: In most NRC meetings that I
20 am invited to, usually had the dates one year and
21 sometimes as much as two years in advance, but this
22 being a smaller meeting, I think six months is not
23 unreasonable. The thought behind that, if you make it
24 much smaller than six months you either have to cancel
25 some other appointments or you have to cancel this

1 one. I think minimum six months, if not more.

2 MS. McINTOSH: Okay, well, let's try to
3 establish the next meeting date in October. It looks
4 like basically the third week of October is the best
5 week to go with.

6 MEMBER DIAMOND: When is that?

7 MEMBER NAG: The third week of October is
8 national meeting for the Radiation Oncology Society.

9 MEMBER DIAMOND: What's the date of ASTRO?

10 MS. McINTOSH: The ASTRO meets -- I'm
11 sorry, do you have that?

12 MEMBER NAG: Yes, it is 16th through 20th
13 of October.

14 MS. McINTOSH: So the week following that
15 week looks like the best week either Tuesday,
16 Wednesday, Wednesday, Thursday.

17 MEMBER NAG: That's the last week of
18 October.

19 MS. McINTOSH: Yes.

20 MEMBER WILLIAMSON: Could we encourage
21 you, Angela to send a confirmation of the final dates,
22 as soon as possible to all of us?

23 MS. McINTOSH: What we would like to do is
24 try to confirm them now --

25 MEMBER WILLIAMSON: I don't have my

1 calendar here. It's really difficult for me to -- I
2 don't have anything, no.

3 MS. McINTOSH: But we're looking at --

4 MEMBER DIAMOND: The week of October 24th?
5 It's okay with me right now.

6 MS. McINTOSH: So right now we can say
7 October 25th and 26th or 26th and 27th?

8 MEMBER WILLIAMSON: I have no idea without
9 my calendar.

10 MS. McINTOSH: So what needs to be done
11 next is that -- let's just say for now, let's go with
12 October 25th and 26th and if that doesn't work, then
13 we'll just try the 26th and the 27th.

14 If that doesn't work, then we're going to
15 have to push it to November. With Thanksgiving and
16 all, it's more difficult.

17 That's basically it for me.

18 CHAIRMAN MALMUD: That completes Angela's
19 report. Is there anything else anyone wants to
20 discuss before we adjourn the meeting?

21 Sally?

22 MEMBER SCHWARZ: I just wanted to ask
23 Angela, is the room available, those days, do you
24 know?

25 MS. McINTOSH: It's too far to project

1 that the room will be available. We will do what we
2 always do. We will put in the request.

3 MEMBER SCHWARZ: Do you want people to let
4 you know if this is acceptable for them?

5 MS. McINTOSH: Right, we're going to go
6 with the first suggested dates of the 25th and the
7 26th and if everyone -- of course, I can follow up
8 with an e-mail, but if everyone can talk away with the
9 knowledge that we're trying for the 25th and the 26th,
10 check your calendars, make sure that there's not a
11 conflict. If there's any conflicts, then we're going
12 to automatically try for the 26th and 27th.

13 MEMBER WILLIAMSON: Could you send an e-
14 mail because I think it will be helpful.

15 MS. McINTOSH: Yes, of course.

16 MEMBER NAG: Now that we have both the NRC
17 building and possibly the hotel for the meeting, if we
18 contact the room over at the NRC building and -- can
19 we use this hotel? The only thing we need to know is
20 the date and if the location -- I don't mind whether
21 NRC or here.

22 DR. MILLER: If we get the date
23 established which I think is most important than what
24 we don't want to do is change the date. So we have
25 three options. We have getting the ACRS/ACNW meeting

1 room, getting the NRC auditorium where we held one
2 meeting, or getting this facility, if it isn't booked.
3 Okay? I guess as long as we agree upon the dates, I
4 think we can accommodate getting a meeting room.

5 MS. McINTOSH: Yes. We can find a venue,
6 if we can just agree upon the dates.

7 DR. MILLER: I think it's more important
8 to lock in the dates at this point.

9 CHAIRMAN MALMUD: Yes.

10 DR. MILLER: I mean we had some
11 disruptions here with the background noise and the
12 microphones, but other than that, I thought it was a
13 reasonable place.

14 MEMBER EGGLI: You should have made a
15 special request for the song fest going on across the
16 way.

17 DR. MILLER: Yes, we didn't pay for the
18 entertainment, so it was great.

19 MR. ESSIG: And I would add, even if this
20 is available, I would consider it to be a last resort,
21 simply because this cost us \$5,000. The other rooms
22 we get for nothing, believe it or not, 5 grand.

23 MEMBER NAG: The other Marriott North has
24 been open, it's possible to have a tentative booking
25 for everyone there and anyone who doesn't like it can

1 cancel.

2 MR. ESSIG: The problem is if we reserve
3 a block of rooms, I've never been convinced that this
4 Committee is willing to stay at the same hotel because
5 you all have your own preferences. I know, Ralph,
6 you've suggested that before, that we have a block of
7 rooms. We can do that on a voluntary basis, and the
8 only thing I have to say for it is that we don't get
9 booked for any -- billed for any rooms that we don't
10 use.

11 MEMBER NAG: But back before when we
12 didn't have any convenient hotel, now that we have a
13 convenient hotel across the street, I think that's
14 different and any other place you can have it held for
15 one month or something and anyone who doesn't want it
16 can cancel it.

17 DR. MILLER: I'd have to pursue whether we
18 can do that through our travel.

19 MEMBER LIETO: I was just going to say if
20 we could set it up with Carlson Travel and let them
21 just handle all of the arrangements, that way it's not
22 something everybody is beating Angela up or Tom about.

23 DR. MILLER: Let's pursue whether or not
24 it can be done. Again, what Tom said, we have to
25 protect against somebody not being able to make the

1 meeting and we've got a commitment to have that room
2 booked.

3 MEMBER LIETO: If you just have it set up
4 such that by X number of weeks beforehand, after that
5 date, you're on your own. If they don't book it, you
6 release it.

7 CHAIRMAN MALMUD: What happens if you book
8 it and have to cancel?

9 MEMBER SULEIMAN: I think Marriott, the
10 last I remember, Marriott has honored the federal per
11 diem. Did anybody stay here?

12 MEMBER EGGLI: I did.

13 MR. ESSIG: And did you get it for federal
14 per diem?

15 MEMBER EGGLI: They honor Government per
16 diem. There were no rooms left, so I opted to pay the
17 delta myself.

18 DR. MILLER: There were no rooms left to
19 Government per diem?

20 MEMBER EGGLI: Yes.

21 DR. MILLER: But they were willing to
22 offer you a room at a higher rate?

23 MEMBER EGGLI: Sure. They all did.

24 MEMBER WILLIAMSON: What's the per diem?

25 MEMBER NAG: \$153.

1 MEMBER WILLIAMSON: I had to pay \$191 and
2 I just had my institution make up the difference so I
3 didn't have a problem there. But rarely have they
4 been able to get into a hotel for the cheaper rate.
5 It's very difficult.

6 MR. ESSIG: But sometimes Carlson is able
7 to do that and I don't --

8 DR. MILLER: We may not have a big enough
9 number of people for them to be able to do it. Like
10 I know --

11 MEMBER LIETO: Unless everybody is doing
12 it on their own as opposed to having 12 -- probably 12
13 people doing it, it might be a little bit -- you might
14 have a little bit of leverage that way.

15 MR. ESSIG: We can certainly talk with
16 Carlson people. They make your flight arrangements or
17 other travel arrangements. They can make the hotel
18 part of the same deal.

19 MS. McINTOSH: One of the advantages of
20 agreeing upon a meeting date this far in advance is
21 that people do know when we're going to have a meeting
22 and can therefore book rooms now.

23 So the key to getting a room is to not
24 wait too late to book it and if we had -- once we've
25 confirmed the date which shouldn't take too long, the

1 next step then would be to book the room.

2 MEMBER NAG: And that is what I had done
3 the last time. It was April 11th and 12th. I had my
4 room at the \$153 rate and then we canceled it. When
5 I canceled that rate and gave the new dates, it was
6 not available.

7 So have to keep the date once we make the
8 dates.

9 CHAIRMAN MALMUD: Well, if it's any other
10 conciliation, all other hotel rooms failed. The
11 Ramada Inn will always take you and the nice thing
12 about the Ramada Inn you enjoy very much getting up
13 early and getting out of there.

14 (Laughter.)

15 I hope that's not for the record. If
16 there's no other serious business, we will adjourn the
17 meeting.

18 Thank you all. Thank you all.

19 (Whereupon, at 4:44 p.m., the meeting was
20 concluded.)

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