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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

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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

SALLY WAGNER SCHWARZ, R.Ph., Member

ORHAN SULEIMAN, Ph.D., Member

WILLIAM VAN DECKER, M.D., Member

RICHARD J. VETTER, Ph.D., Member

JEFFREY F. WILLIAMSON, Ph.D., Member

NRC STAFF PRESENT:

THOMAS H. ESSIG, Designated Federal Official

CHARLES L. MILLER

IVELISSE CABRERA

TRISH HOLAHAN

DONNA-BETH HOWE, Ph.D.

ANGELA R. McINTOSH

RANDY RAGLAND

RONALD ZELAC, Ph.D.

ALSO PRESENT:

DOUGLAS KONDZIOLKA, M.D., IRSA

DAVID LARSON, M.D., ASTRO

MICHAEL A. SHEETZ, University of Pittsburg

GERALD A. WHITE, M.S., AAPM

PAUL WALLNER, ASTRO

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

consideration.

CHAIRMAN MALMUD: Please do.

MEMBER WILLIAMSON: Is that agreeable to everybody?

CHAIRMAN MALMUD: Dr. Nag?

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

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

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

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

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

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

CHAIRMAN MALMUD: Is that in the book?

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

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

MEMBER WILLIAMSON: What is in the book --

CHAIRMAN MALMUD: It's dated March 24th.

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

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

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

CHAIRMAN MALMUD: Thank you.

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

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

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

MEMBER LIETO: Yes, I do.

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

CHAIRMAN MALMUD: Sure.

(Pause)

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

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

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

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

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

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

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

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

MEMBER WILLIAMSON: Okay.

MEMBER NAG: When we had it that the

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

MEMBER WILLIAMSON: So the word target volume and --

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

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

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

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

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

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

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

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

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

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

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

(Pause)

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

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

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

MEMBER DIAMOND: Do you want to respond?

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

MEMBER NAG: But then --

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

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

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

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

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

CHAIRMAN MALMUD: Al?

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

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

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

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

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

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

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

MEMBER WILLIAMSON: The one concern --

CHAIRMAN MALMUD: Dr. Suleiman?

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

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

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

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

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

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

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

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

MEMBER NAG: No, not really.

MEMBER WILLIAMSON: -- more wiggle room.

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

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

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

MEMBER NAG: That is what I had suggested.

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

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

CHAIRMAN MALMUD: How many slides?

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

CHAIRMAN MALMUD: If there are no

questions, how many slides do you have?

MEMBER NAG: Probably about 25 slides.

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

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

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

CHAIRMAN MALMUD: Dr. Vetter.

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

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

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

MEMBER NAG: Deviates.

MEMBER VETTER: Deviates.

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

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

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

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

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

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

MEMBER DIAMOND: But again --

MEMBER NAG: Wrong site, the wrong site --

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

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

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

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

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

MEMBER DIAMOND: Correct.

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

MEMBER NAG: Right.

CHAIRMAN MALMUD: And how do you disagree with it?

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

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

MEMBER NAG: The treatment site, the treatment site.

CHAIRMAN MALMUD: "In the treatment site"?

MEMBER NAG: Right.

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

Williamson, "treatment site"?

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

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

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

CHAIRMAN MALMUD: Therefore you would -- excuse me.

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

CHAIRMAN MALMUD: Thank you, but you --

MEMBER NAG: So basically, we agree.

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

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

CHAIRMAN MALMUD: Awkward.

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

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

MEMBER DIAMOND: I'm a happy man.

CHAIRMAN MALMUD: And Dr. Williamson, do you?

MEMBER WILLIAMSON: No.

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

MEMBER WILLIAMSON: Ralph has been patiently waiting.

CHAIRMAN MALMUD: Ralph?

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

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

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

CHAIRMAN MALMUD: Thank you, Dr. --

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

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

MEMBER LIETO: Thank you.

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

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

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

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

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

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

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

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

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

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

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

credentialing process?

DR. ZELAC: I cannot comment.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

CHAIRMAN MALMUD: Mr. Lieto?

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

CHAIRMAN MALMUD: Please.

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

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

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

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

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

MEMBER DIAMOND: In what sense?

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

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

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

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

CHAIRMAN MALMUD: But you see --

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

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

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

CHAIRMAN MALMUD: Thank you, Dr. Zelac.

MEMBER NAG: May I?

CHAIRMAN MALMUD: Yes.

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

CHAIRMAN MALMUD: Yes.

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

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

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

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

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

MEMBER NAG: Yes.

MEMBER WILLIAMSON: I think that's a good

idea.

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

MEMBER NAG: That's fine.

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

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

So it's extremely important as -- and

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

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

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

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

CHAIRMAN MALMUD: Dr. Nag?

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

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

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

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

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

MEMBER WILLIAMSON: Well, we all have your handout.

CHAIRMAN MALMUD: We have your handout.

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

CHAIRMAN MALMUD: Okay.

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

to take me a minute here.

MEMBER LIETO: Mr. Chair?

CHAIRMAN MALMUD: Mr. Lieto?

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

MEMBER NAG: Yes.

CHAIRMAN MALMUD: Yes.

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

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

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

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

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

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

CHAIRMAN MALMUD: Dr. Zelac?

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

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

MEMBER DIAMOND: Okay, that's silly.

DR. ZELAC: It is silly.

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

DR. ZELAC: Is anyone from General Counsel present?

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

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

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

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

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

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

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

CHAIRMAN MALMUD: Mr. Lieto?

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

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

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

MEMBER DIAMOND: I concur.

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

MEMBER WILLIAMSON: No.

MEMBER DIAMOND: Oh, Jeff.

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

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

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

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

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

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

CHAIRMAN MALMUD: Dr. Zelac?

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

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

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

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

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

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

applies.

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

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

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

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

MEMBER NAG: I would --

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

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

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

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

CHAIRMAN MALMUD: Right.

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

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

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

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

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

except for permanent implant.

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

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

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

CHAIRMAN MALMUD: Thank you. Dr. Howe?

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

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

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

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

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

CHAIRMAN MALMUD: Dr. Nag.

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

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

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

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

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

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

MEMBER NAG: I think, I think Dr.

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

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

MEMBER WILLIAMSON: That's a very good summary.

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

in --

MEMBER LIETO: That was the issue I was addressing.

CHAIRMAN MALMUD: Okay, so that there is agreement.

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

MEMBER WILLIAMSON: I certainly am not disagreeing.

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

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

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

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

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

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

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

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

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

MEMBER WILLIAMSON: That was the intent.

CHAIRMAN MALMUD: Dr. Zelac?

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

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

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

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

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

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

CHAIRMAN MALMUD: Thank you.

MEMBER WILLIAMSON: Is that okay?

CHAIRMAN MALMUD: Yes.

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

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

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

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

CHAIRMAN MALMUD: Discussion of this item.

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

CHAIRMAN MALMUD: Dr. Diamond?

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

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

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

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

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

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

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

CHAIRMAN MALMUD: Agreed.

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

CHAIRMAN MALMUD: Okay, Dr. Suleiman.

MEMBER SULEIMAN: The paragraph bothers me.

MEMBER DIAMOND: The second sentence bothers me.

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

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

MEMBER SULEIMAN: That's how I read it.

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

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

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

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

MEMBER DIAMOND: I concur.

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

MEMBER DIAMOND: To the patient.

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

MEMBER DIAMOND: Patient reporting.

MEMBER WILLIAMSON: -- patient reporting, yeah.

MEMBER DIAMOND: Patient reporting.

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

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

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

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

MEMBER NAG: May I?

CHAIRMAN MALMUD: Dr. Nag.

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

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

CHAIRMAN MALMUD: Al?

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

CHAIRMAN MALMUD: Dr. Zelac?

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

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

CHAIRMAN MALMUD: Thank you. Dr. Eggli?

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

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

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

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

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

sense.

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

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

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

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

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

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

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

MEMBER LIETO: No, no.

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

PARTICIPANT: To move forward?

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

MEMBER NAG: Yes.

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

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

Next item.

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

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

CHAIRMAN MALMUD: Dr. Nag?

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

CHAIRMAN MALMUD: Dr. Eggli?

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

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

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

CHAIRMAN MALMUD: Dr. Diamond?

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

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

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

CHAIRMAN MALMUD: Dr. Williamson.

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

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

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

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

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

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

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

MEMBER DIAMOND: What's your solution, Doug?

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

MEMBER WILLIAMSON: May I --

MEMBER DIAMOND: We have to do something, though.

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

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

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

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

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

MEMBER WILLIAMSON: Yes.

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

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

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

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

MEMBER NAG: Yes.

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

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

CHAIRMAN MALMUD: So the committee is reaffirming --

MEMBER LIETO: For all modalities.

CHAIRMAN MALMUD: For all modalities?

MEMBER WILLIAMSON: Except permanent brachytherapy.

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

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

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

CHAIRMAN MALMUD: Okay, Dr. Suleiman?

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

what the other one was.

CHAIRMAN MALMUD: You are correct.

MEMBER WILLIAMSON: Correct.

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

MEMBER WILLIAMSON: Barry.

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

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

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

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

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

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

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

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

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

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

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

I work at the University of Pittsburgh.

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

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

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

David Larson who will speak after me is a

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

the key is the brain anatomy in understanding that.

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

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

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

The outcomes published with radiosurgery

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

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

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

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

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

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

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

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

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

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

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

I also want to take a step back and tell

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

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

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

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

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

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

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

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

Here's a patient of mine with obsessive-

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

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

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

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

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

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

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

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

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

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

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

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

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

Thank you very much.

[Unmic'd audience question.]

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

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

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

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

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

MEMBER NAG: Yes.

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

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

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

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

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

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

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

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

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

DR. KONDZIOLKA: That's the problem. The

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

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

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

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

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

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

DR. KONDZIOLKA: Not in the brain.

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

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

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

CHAIRMAN MALMUD: Yes, Dr. Williamson.

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

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

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

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

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

MEMBER WILLIAMSON: Within your LCMG.

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

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

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

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

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

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

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

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

Is there a corresponding problem in your mind?

DR. KONDZIOLKA: There is.

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

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

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

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

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

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

DR. KONDZIOLKA: Of the NRC.

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

DR. KONDZIOLKA: Oh sure.

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

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

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

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

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

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

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

Yes?

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

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

CHAIRMAN MALMUD: Any other questions for our guest?

Dr. Eggli?

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

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

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

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

And so the slippery slope is that now when

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

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

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

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

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

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

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

(Off the record.)

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

MEMBER RAIZNER: I have a little bit of a

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

credential.

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

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

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

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

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

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

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

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

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

Did I summarize what your goals are?

DR. KONDZIOLKA: Yes.

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

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

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

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

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

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

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

Dr. Zelac?

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

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

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

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

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

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

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

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

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

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

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

Dr. Larson?

DR. LARSON: Is this working okay? Good

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

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

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

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

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

Radiation Oncology at the University of Pennsylvania School of Medicine.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

biology, physics, treatment planning or safety components.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

On the day of treatment, the plan was

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Dr. Vetter?

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

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

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

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

CHAIRMAN MALMUD: Dr. Wallner?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(Off the record.)

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

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

Does anyone wish to begin? Yes, please.

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

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

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

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

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

Parkinson's Disease and so on.

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

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

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

The other way to do it which is the

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

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

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

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

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

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

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

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

CHAIRMAN MALMUD: Dr. Diamond?

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

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

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

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

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

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

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

MS. EMERICK: Yes.

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

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

board.

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

MS. EMERICK: Yes.

MEMBER DIAMOND: Who are they?

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

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

MS. EMERICK: Yes.

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

MS. EMERICK: Just this morning.

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

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

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

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

MS. EMERICK: We don't have an application. Pittsburgh has applications in for different things and I'm not sure what that paragraph was addressing.

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

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

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

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

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

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

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

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

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

Where is this place?

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

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

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

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

MS. EMERICK: That's fine --

MEMBER DIAMOND: Of Cobalt-60 sources --

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

MEMBER DIAMOND: We'd like to know about

it.

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

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

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

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

MR. ESSIG: No, I'm not.

MEMBER DIAMOND: They don't seem to know.

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

MR. ESSIG: They do.

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

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

stated facilities and we couldn't pursue it.

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

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

MS. FLANNERY: Correct.

MEMBER DIAMOND: I'll try again.

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

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

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

MS. FLANNERY: Right.

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

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

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

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

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

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

MS. EMERICK: Different center.

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

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

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

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

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

CHAIRMAN MALMUD: Would you respond again, please?

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

CHAIRMAN MALMUD: Mr. Lieto?

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

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

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

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

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

CHAIRMAN MALMUD: Dr. Diamond, which page?

MEMBER DIAMOND: Twenty-eight.

CHAIRMAN MALMUD: Twenty-eight. Thank you.

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

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

MEMBER DIAMOND: I'm reading --

MS. EMERICK: You.

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

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

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

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

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

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

MS. EMERICK: I did pick up the phone and

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

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

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

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

MS. EMERICK: That's all.

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

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

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

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

MEMBER DIAMOND: Thank you.

MS. EMERICK: That was why you were called.

CHAIRMAN MALMUD: Any other questions? Comment?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Thank you very much.

CHAIRMAN MALMUD: Thank you. Dr. Howe?

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

CHAIRMAN MALMUD: Thank you, Dr. Howe.

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

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

We support the team approach. We also

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

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

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

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

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

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

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

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

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

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

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

Lastly, to say something about physical

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

(Laughter.)

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

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

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

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

CHAIRMAN MALMUD: Thank you. Other comments?

Dr. Raizner?

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

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

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

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

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

Thank you.

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

Oh yes. Will you please introduce yourself?

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

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

MR. RAGLAND: Yes.

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

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

MEMBER LIETO: Well, I think the first

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

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

MEMBER LIETO: That's correct.

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

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

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

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

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

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

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

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

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

MEMBER LIETO: Mr. Chairman?

CHAIRMAN MALMUD: Yes, Mr. Lieto.

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

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

Do I interpret that correctly?

MR. ESSIG: Yes.

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

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

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

Small bites. Excuse me, Dr. Suleiman.

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

CHAIRMAN MALMUD: I think that we owe the parties involved a response and maybe even a recommendation, but it would be premature for us to come to that conclusion at this time, given the brief time that we've had exposure to what they have shared with us. We meet three times a year and we also have conference calls available for subcommittees or committees if we wish. And we can bring the issue forward. This is not a pressing issue at the moment that requires an immediate decision, is it?

MR. ESSIG: That's correct. And I think

what we'll do is review the totality of the meeting minutes and decide whether or not we need to seek or seek some advice from the committee.

CHAIRMAN MALMUD: Thank you. Was there a comment you wish to make?

MR. SHEETZ: Yes, Mike Sheetz, University of Pittsburgh again. I do want to make a comment and maybe direct a more specific question to the committee. We have twice submitted for an amendment request for an exemption to the physical presence requirement to allow one of our qualified neurosurgeons to be able to substitute for the radiation oncologist, after the initiation of the treatment, to be physically present so the oncologist could leave the area. This was refused both times.

We submitted a third request and because we have multiple units, part of the justification was that we may have more than one treatment going on at the same time and the Commission responded back approving it, but with several conditions. There had to be at least two treatments going on at one time. At each console must be a neurosurgeon and then the radiation oncologist could float back and forth which really didn't gain us any ground. It didn't relieve the oncologist to do other things or be involved in

dose treatment planning and so forth.

So I guess the specific question I have to the committee is and I think this has been posed previously, can we make a generic, this may be proposed rulemaking, but -- or can you make general guidance that a qualified neurosurgeon with the appropriate training in gamma knife procedures and emergency procedures substitute for the radiation oncologist for the current physical presence requirement? Is that an appropriate exemption and/or maybe an initiation for proposed rule -- maybe the response would be no, that has to be proposed rulemaking and that would be the process. So I'm looking for guidance on that.

Thank you very much.

CHAIRMAN MALMUD: Dr. Diamond?

MEMBER DIAMOND: Mr. Sheetz, I guess I'm a little confused. My understanding was and I forget, this was about two years ago or so now, that the request was to obviate the need for a radiation oncologist to be at each of the consoles because of patient needs elsewhere and I thought that the ACMUI gave you a response which is exactly what you wanted. I remember having that discussion. I thought the specific request was to go and lessen the burden and

I seem to remember that's exactly what we intended to give you.

DR. WALLNER: Mr. Chairman, if I could make a comment.

CHAIRMAN MALMUD: Dr. Wallner.

DR. WALLNER: My understanding is that the initial request for the exemption for the University of Pittsburgh was based on their premise that radiation oncologists were not available or not interested in being available. I believe the Committee has in front of it a letter from Dr. Flickinger and Dr. Greenberger from the University of Pittsburgh that completely disavows the Department of Radiation Oncology of that position. That is not the position of the Department of Radiation Oncology at the University of Pittsburgh. The authorized user must be present.

CHAIRMAN MALMUD: Dr. Miller?

DR. MILLER: Getting back to the previous question of is there any action today that the Committee needs to take, leave two things on the table. One, there are many issues that the staff asks the Committee to undertake to advise us. But there is nothing in the by-laws that it's intended, I think, that if the Committee ever sees issues that they that

they need to advise the staff on or make recommendations to the staff on, from your own expertise, that need addition with regard to issues that are under NRC's purview, you're free to do so.

So based upon the information that you heard today, if you chose to do that, you would be within your rights. You would not have to have the staff do that. I'm not asking that you do that, I'm just offering that there's two ways that issues that are brought before the Committee can be pursued.

MEMBER NAG: Who is the NRC staff on this issue? Who is the assigned NRC staff?

DR. MILLER: They would be members of my staff --

MEMBER NAG: I know that. Anyone specific who had been assigned this task?

DR. MILLER: I'd have to -- Tom, do you know?

MR. ESSIG: Assigned the task of --

MEMBER NAG: You know, the physical presence in gamma knife and that issue.

MR. ESSIG: We have a couple of staff that are certainly knowledgeable, and Dr. Howe and Dr. Zelac --

MEMBER NAG: No one person? You know we

had the expert for the medical events, we had someone to talk to.

DR. MILLER: Dr. Nag, I think your question is does the NRC have any staff members assigned to studying the issue with regard to making a recommendation.

We received various letters as has been brought forward to the Committee today and staff evaluates that information and decides if we need to take any action or we need to engage the Committee on making any action.

But as I said before, based upon the evidence that was put before you today, the Committee is free to make a motion and pass a motion to undertake such an activity, if you see fit to do so.

MEMBER DIAMOND: This is Dr. Diamond again. So Charlie, when I was listening to Dr. Kondziolka, many of his comments related to quality assurance issues, particularly at non-hospital based centers in which there's a concern that the oversight and that the patterns of care may not be optimal and that's a real issue.

Now a strict interpretation of our mission statement would say that some of these issues were outside of our purview, but if I understand you

correctly, perhaps there's some wiggle room, for example, to make recommendations regarding that the Advisory Committee believes that it is inappropriate to exclude a neurosurgeon, be present as part of the procedure. Are you saying things like that can be integrated? Because I think we all agree in unanimity that it essential for the neurosurgeon to be there as well. In any situation where that's not occurring, must cease. And the question is how can that be done?

So again, is there any methodology that without violating our charter, we can go and make progress on that issue?

And again, it's kind of difficult now that it's already 4:20 and some of us have planes to catch, but --

DR. MILLER: I guess my reaction is I think there is as long as we stay within NRC's regulatory responsibilities and we don't encroach on the practice of medicine. Then I think that would be outside this Committee's functions. I don't know if that answers your question, Dr. Diamond.

MEMBER DIAMOND: I don't think we ever considered this before, so it's something to think about.

CHAIRMAN MALMUD: May I take us back a

step? The current standards require the authorized user be present for the entire procedure. That authorized user may be a radiation physicist, a radiation oncologist -- who is the authorized user? The radiation oncologist. And is there any other authorized user, in general terms? There are specific exceptions, are there not? Or is it always a radiation oncologist?

DR. MILLER: Always radiation oncologist.

CHAIRMAN MALMUD: Always radiation oncologist. And then we have a letter dated April 6th from Drs. Herrod, Greenberger and Flickinger which says that due to a misunderstanding we were given to believe that they were supportive of not having to have the proposal that was put before us earlier and in fact, they are not supportive of that proposal.

And in fact, it says "for the record, the University of Pittsburgh has adequate physician and physicist staffing levels within the Department of Radiation Oncology and follows all NRC regulations including fulfilling the physical presence requirements for radiation oncologists during gamma stereotactic radiosurgery."

So we do agree that that is a standard that we're not budging from at the moment? Or are

there exceptions to that standard anywhere in the United States?

MR. RAGLAND: I believe there are several facilities that have an exemption where an authorized user, where a neurosurgeon could substitute for an authorized user as long as it went for more than 50 percent of the treatment and the authorized user was immediately available.

CHAIRMAN MALMUD: Dr. Howe?

DR. HOWE: We granted an exemption to one licensee, that they had to start the procedure with the authorized user and the authorized medical physicist and the authorized user had to be physically present for 50 percent of the treatment.

CHAIRMAN MALMUD: May I ask why the exemption was granted?

DR. HOWE: I believe the licensee stated medical care for other patients as part of the reason that the authorized user may be called away to participate in patient treatment, but it wasn't supposed to happen all the time and they guaranteed that the authorized user would be there at least 50 percent of the time so that for very long procedures, the authorized user could be called away in need of emergency.

MEMBER DIAMOND: Kansas City?

DR. HOWE: Kansas City would not be an NRC licensee. I think it's in Region 1. Region 3.

CHAIRMAN MALMUD: Dr. Vetter.

DR. HOWE: And we also granted an exemption to Pittsburgh for multiple uses.

MEMBER VETTER: In the case of that exemption, is the neurosurgeon present?

DR. HOWE: Yes.

CHAIRMAN MALMUD: So there's an exemption in which the neurosurgeon can be present and the radiation oncologist absent for 50 percent of the time?

DR. HOWE: Yes, because the neurosurgeon would be considered to be the medical person there that would respond to medical emergencies.

CHAIRMAN MALMUD: Is that neurosurgeon declared an authorized user?

DR. HOWE: No.

CHAIRMAN MALMUD: No.

DR. HOWE: The neurosurgeon has never been an authorized user. They may have had an authorized neurosurgeon, but not an authorized user.

CHAIRMAN MALMUD: And did someone mention

there was a second exemption?

DR. HOWE: We granted a second exemption to the University of Pittsburgh for multiple units being used at the same time and in that case we allowed the neurosurgeon to take the place of the authorized user at one of the sites, but the idea was that the authorized user had to be physically present at the other unit so that they could be called to the -- if there was an emergency at the second unit, they could respond and there would still be a neurosurgeon there and there would still be an authorized medical physicist.

CHAIRMAN MALMUD: So they would float between two units in the same building?

DR. HOWE: They were in the same suite. The suite is very large, so you need to get that concept. The gamma knife units are about 100 feet apart.

CHAIRMAN MALMUD: Thank you. Dr. Miller, did you want to give us any other advice?

DR. MILLER: Take two and go to the right. I think that the issue is twofold. One I have to ask myself to evaluate it more and decide if there was an issue that requires any kind of action on the part of NRC. But as I said earlier, I'm not asking you to do

so, but if the Committee is a body of wisdom, medical wisdom, feels that based upon what you've heard today, there's an issue where you think NRC needs to take some kind of regulatory action or further evaluation, you're free to provide, as a body, that advice that we should take that on.

I'm not in a position today to say one way or another. I would need personally I would need further evaluation from staff before I would make such a statement.

CHAIRMAN MALMUD: Dr. Williamson? I was going to ask if the members of the Committee felt that they wish to make a decision at that time or have additional opportunity to discuss this amongst ourselves?

I've given you two options. Does the Committee feel that it would want to vote on this issue now?

Dr. Williamson?

MEMBER WILLIAMSON: I really think the underlying issue is not a small bite. I think it's a major philosophical issue that drives at the very heart of the regulatory system and involves fundamental discussion about where the boundary is between the scope of NRC's regulatory activity and

what is practice of medicine. I don't think it's a simple yes or no kind of thing. I certainly feel uncomfortable about dealing with it under these circumstances and I think it would be a major effort of this Committee to take on this without a strong regulatory need being established. That would be my observation. I think we would have a very limited chance of success.

CHAIRMAN MALMUD: Dr. Suleiman?

MEMBER SULEIMAN: Well, I thought yesterday we heard that the caregiver filed for an exemption, see if we get lots of exemptions and then propose possibly rulemaking changes in the future if appropriate.

I now hear that we've got one situation where there has been an exemption granted. It sounds to me like there's a process already in play and there's a way to address these issues and let's just let things -- if more institutions want to file for that exemption since the precedent seems to have been set at least once, if you get a flood of these across the country or whatever, maybe there's a need to address this further. Or, if this is an isolated case, then we can just let things work out rather than discussing it here.

CHAIRMAN MALMUD: I must say that I remain puzzled as to why Pittsburgh is asking for an exemption when the radiation oncologists at Pittsburgh say there is not a need for one.

DR. KONDZIOLKA: Can I address that, Dr. Malmud?

CHAIRMAN MALMUD: Yes, please.

DR. KONDZIOLKA: I was going to remain quiet on that letter, but since you brought it up, I'd like to address your puzzled aspect of it.

I, too, was very puzzled by it. I was made aware of this letter at quarter to 1 this afternoon and I think the key person who signed that letter is Dr. Flickinger and since it will go into the record here, I'll say about one minute on this.

I spend 90 percent of my work week with John Flickinger who is a superb and brilliant radiation oncologist and close personal friend. I also say I've had lunch with already two times this week and he never brought that letter to my attention. Not once since it was apparently signed on April 6th. So I phoned him up at a quarter to one this afternoon before I came in this room and I said, "John, what's with this letter?" I said I agree with the first paragraph. I agree with the second paragraph. In

paragraph three, what exactly is the issue that you are objecting to, because there's a number of issues because the letter specifically doesn't say that. And the issue was the physical presence of the radiation oncologist. I said well, John, what we've been talking about is the ability for you to walk across the hall to do a consult and come back in 10 minutes and right now you are not allowed to do that. And don't you want to be able to do that and I sit there monitoring our patient for the 10 minutes. That's what we're talking about here, not breaking up the team, not changing patient quality.

He says well, this letter came from the standpoint that ASTRO leaned on the Department on Radiation Oncology to make a comment and as John said, I was forced to sign it. Now he did sign it and it's in the record and that's fine and if he truly believed that this was not in his best interests or the Department's, he shouldn't have signed it, but he did and so that's why I was not even going to comment on it, but that is the genesis of it. I also want to say that Dr. Wallner mentioned what with the University of Pittsburgh standing, it's not the University of Pittsburgh standing, but it is the official Department of Radiation Oncology standing. It's not the

Department of Neurosurgery, nor have you heard it from the Radiation Safety Officer at the University of Pittsburgh either.

CHAIRMAN MALMUD: Thank you. The letter is signed by the Chairman of the Department of Radiation Oncology at Pittsburgh who I assume outranks the professor. And that's Dr. Greenberger and also the Vice Chairman for Clinical Services, Dr. Herrod. So the letter is signed by the three. Is that the size of the department, three men?

DR. KONDZIOLKA: You're correct, it's a large department and the other two are the clinical and academic leaders of the department.

CHAIRMAN MALMUD: Mr. Lieto?

MEMBER LIETO: It still, I think supports what you just said is that the testimony that was just given, there's not a problem with adequate physician physicist staffing. I think we just heard here that they agreed with the first two paragraphs, so again, I think it gets back to the point that was brought up earlier is why the exemption for Pittsburgh. They have adequate physician and physicist staffing to meet the current regulations.

And my second point is that I think we should -- we might want to table this until we get

some further input and so forth because I believe it's a requirement, Part 35, that an authorized medical physicist is present for these procedures, so if you're going to try to establish a generic exemption, basically what you're doing is requiring a change in rulemaking because you can't exempt all medical -- the requirement for all medical physicists being present.

CHAIRMAN MALMUD: Dr. Miller and then Dr. Nag.

DR. MILLER: I agree one hundred percent with what Mr. Lieto just said.

CHAIRMAN MALMUD: Thank you.

MEMBER NAG: I remember the discussion in ACMUI. I'm not sure exactly when. I don't have my notes, but the ACMUI had felt that if in this particular situation where there are two machines right next to each other and one person is right there who is basically within hearing distance of both, that person could serve to oversee both. I mean this is quite opposed to any other place where you have one machine and someone asks not to be in that machine at all.

Here, you have two machines and one person could oversee, one radiation oncologist could oversee both of them and one neurosurgeon at the other machine

and I remember that discussion quite well and we felt that was reasonable and I know I voted yes.

CHAIRMAN MALMUD: Thank you. I must tell you that I won't make the decision, the Committee will, but I, as chair, am still troubled by this because there are two exemptions that I do not fully understand and I do understand this request which is essentially very similar to having a staff anesthesiologist float between two rooms with a nurse anesthetist doing anesthesia because the two rooms are adjacent to each other and the staff anesthesiologist could not do both rooms at one time and if that's what this is analogous to, I can understand that we can discuss that and perhaps accept that. But I would still like to see the basis of the other two exemptions so we can bring the whole thing to a full discussion and then make a wise decision, carefully first discussed with the facts at hand. I don't feel in that position at the moment.

My question is do any of you feel comfortable with this at the moment and wish to move on it?

Dr. Diamond?

MEMBER DIAMOND: Since I'm the one that actually wrote the ACMUI note in support of the

application, I unfortunately, as I get older, can't remember all the details from two years ago, but I would be happy to go through my records at my office and distribute that letter to everyone. As I seem to recall, the tenor of the request was was the premiere center of the country doing this or adding a third unit. This unit is physically very close to the other two units. All the members of the treatment team being the authorized user, neurosurgeon, the physicist are all in agreement that this is a useful and reasonable exemption request and based upon that tenor, as I recall, the entirety of this Committee, felt that that was reasonable.

Now again, I can't remember the details, but I do have the letter at my office and I'd be happy to circulate it.

CHAIRMAN MALMUD: And I would love to see it, because I think we need more data in front of us so we can make the correct decision and serve all parties well.

I have no preconception about what the outcome would be.

Dr. Williamson?

MEMBER WILLIAMSON: I would make a motion that our mid-meeting conference call we ask, one of

the staff be asked to review the history of these license amendments at the University of Pittsburgh and previous ACMUI motions on the matter so that we could determine whether there is any decision or proposal to be made and I would then as a second part of my motion propose we table this discussion for now pending that review.

CHAIRMAN MALMUD: Is there a second to Dr. Williamson's motion?

(Second.)

CHAIRMAN MALMUD: All in favor?

(Ayes.)

Any opposed?

(No response.)

Any abstentions?

(No response.)

The motion carries. We will bring this to our next meeting, whether it be a publicized conference call or this meeting and with more facts at our fingertips.

Thank you very much, and also appreciation to each of our guests who presented varying positions on this issue today. You each expressed your interests and concerns very eloquently and given us a lot to think about and we're trying to come to a

conclusion as soon as possible.

If we may then move on to the next agenda item which is that of Angela McIntosh.

MS. McINTOSH: Thank you, Dr. Malmud. The purpose of my discussion is just to go over -- to sort of summarize what was discussed today and to give a very rough overview of some of the action items and recommendations. I'm working from raw notes so I'm not going to be able to give you -- I'm not going to be able to cover everything and give you a thorough overview because our scribe, although she does a fantastic job, she's not -- it's not a word for word capturing of what occurred here at the meeting. That's the purview of the court reporter, and of course, that transcript is not going to be back for several days, so if there's something that anyone remembers, then just feel free to speak up and say oh yes, we agreed to this or we agreed to that.

What I'm going to start off with is just very quickly going over what was recommended and the action from the October 2004 meeting and some of the action items that were agreed upon at that meeting and give you a status update of that and then move on to what occurred at this meeting.

There were several action items and

recommendations made at the October 2004 meeting. The first one on my list was a recommendation made in association with the agenda topic radioimmunotherapy and microsphere therapy. What happened though during the course of discussion somehow discussion shifted to the C-Solectron permanent implant device so no actual recommendation was made in association with the agenda topic.

In association with -- well, the recommendation that came from the discussion of the C-Solectron permanent implant remote afterloader device was that the NRC staff continued to regulate permanent prostate brachytherapy in 10 CFR 351000, but used 35400 as the regulatory framework for creating guidance while adding elements of 35600 as necessary.

MEMBER NAG: I think you -- it should be not permanent prostate brachytherapy but permanent afterloader because permanent prostate brachytherapy like when the prostate brachytherapy review. Here we are talking about the nucleotron's first afterloader permanent prostate brachytherapy. Otherwise, it's not. Really, permanent prostate brachytherapy is under 35600.

MEMBER WILLIAMSON: I agree with Dr. Nag. The way it reads here is all permanent prostate

brachytherapy, regardless of whether it uses a computer-assisted device or not, should be continued to be regulated by 351000 which is absolutely false. It is not now nor ever has been regulated by 1000. It's only this very special niche in permanent implants, so I think it needs to be clarified that permanent implant via robotic seed insertion mechanisms continue to be.

MEMBER NAG: I think the permanent afterloader --

MEMBER WILLIAMSON: Yes.

MEMBER NAG: The word afterloader should be somewhere in there.

Permanent prostate brachytherapy by afterloader.

MS. McINTOSH: By afterloader?

MEMBER NAG: Something like that. It's not all prostate brachytherapy.

MS. McINTOSH: Okay.

MEMBER NAG: Brachytherapy is 99.9 percent of all prostate brachytherapy is done by the -- under 35400. There's only one special kind of prostate brachytherapy by a new machine that we are referring to here.

MS. McINTOSH: Okay, we can adjust that

wording, but the response that we gave to that recommendation was that we agreed with ACMUI's approach with aligning the guidance for the C-Selectron closer to the requirement and 35400 and 600, but the guidance, the development of it was on hold because of a lack of a licensing request for this particular modality.

MEMBER WILLIAMSON: I think when it gets ready to move again, it would be prudent to reconstitute the New Technology Subcommittee or whatever we called it to look at that because there was a strong concern that the proposed licensing guidance was incredibly complicated and much more restrictive in the practice of manual brachytherapy and it went beyond the scope of that instrument.

MS. McINTOSH: Thank you. The second recommendation on the list has to do with the NRC staff asking the ACMUI for advice on creating any guidance in association with the use of iodine seeds as markers in breast cancer tumors and as everyone knows we really couldn't move forward with that at this meeting because we feel that a key player, a key resource, Robert Gallaghar, was not able to be here at this meeting, so our move forward is to schedule a teleconference sometime between now and the fall

meeting or we could always adjust that and rediscuss it at the fall meeting, but in any case, to move on it at the earliest in a teleconfernece between now and the fall meeting.

MEMBER VETTER: Before that conference call, could you make it very clear what it is that you're seeking from ACMUI, in the notice of the conference call?

MS. McINTOSH: Yes. The next recommendation on the list, actually about the next three recommendations on the list were made in association with the rule that is now final and so our basic response to the recommendations on page 3 and the recommendation 200505R on page 4 was that we will consider action -- we will process this action in accordance with how we process all comments during the comment period of any rule. And so the final rule is out and the Commission has made a determination on those action items, so really the answer to those items are contained in the final rule.

The next item on the list, the next recommendation, proposed change to the abnormal occurrence criteria, the ACMUI recommended that we express dose and rem rather than rad in response to the proposed criteria that we presented to you and

that we move to use the term the capture of events that involve the medical administration of by-product material.

Staff, after considering the ACMUI's recommendation, believed that it's best to leave the expression of dose in terms of absorbed dose rad rather than rem. We just took a look at the kinds of therapies, anticipated therapies in the future and we just felt that rad was an overall better term to use.

MEMBER NAG: Which page is this?

MS. McINTOSH: This is page 4. And regarding the ACMUI's recommendation that we require the reporting of events involving the medical administration of material, we also felt that it was better to keep the existing language that requires reporting of medical events because in order for an event to be an OA, it has to be a medical event first. So we just felt it was better that we not change that.

Starting with page five, there was a recommendation that the ACMUI made in response to Dr. Vetter's presentation on the ICRP recommendations and the ACMUI recommended that the ICRP maintain the 500 millirem dose limit to pregnant workers and Dr. Vetter took that recommendation to the ICRP meeting on October 19.

I'm sorry, I misspoke. The Advisory Committee on Nuclear Waste was hosting this meeting and Dr. Vetter took your recommendation to the Advisory Committee on Nuclear Waste. Thank you.

The next item on the list is an action item, a request for ANP status that was forwarded to us from Newark beth Israel Hospital. The ACMUI really did not have much to say about that. The ACMUI reviewed the application and recommended that staff not grant status to the individual and we agreed.

The next item on the list concerning dose reconstruction, a Dr. Sherbini, Sami Sherbini gave a presentation on the staff's response to -- he gave a presentation finalizing our reaction to the dose reconstruction effort that the Commission gave us an assignment to respond to and it was made mention in the meeting that the ACMUI had not seen the actual hard copy response and that was requested at that meeting and we did supply the ACMUI with a copy of our conclusion. So that item was closed out at the meeting.

The next item on the list is another, next two items are action items. The top one, medical event review of iodine events. We got some feedback from the ACMUI on that. We asked the ACMUI to review

the medical events involving radioiodine or medical events and of course, the subcommittee met, came back and gave us several recommendations which Dr. Eggli presented to us today, so we simply have -- we have that information now. You've already forwarded that to us and I believe -- I remember there being a specific recommendation regarding dose calibrators made in some capacity, but in any case, all of your recommendations are contained within Dr. Eggli's presentation, so staff has the answer to that request.

The next item on the list, this item, I believe the staff, it was made specific to Mr. Lieto and I believe we just basically backed off of this one. It says that Mr. Lieto would search the NRC's Nuclear Events Database and help frame the response regarding medical events and what to do to reduce them.

We've got the response, basically, so I don't believe that specific action was carried out or was it?

MEMBER LIETO: I think it was in relation to the I-131 medical event, but in reading this, I'm getting the impression that the intent may be that you're requesting an on-going like maybe annual review and submission to the ACMUI? Or is that something you

want to talk about?

MS. McINTOSH: That's something we can talk about. I remember from the last meeting sort of I think he volunteered to do that. I don't think that we specifically asked you to do that.

MEMBER LIETO: Dr. Vetter?

MEMBER VETTER: I could be in error. My recollection was that the subcommittee was appointed to look at I-131 and Ralph asked a question about what about other events and he basically volunteered or got volunteered to look at other events other than I-131.

And I think it was just a one time thing.

MS. McINTOSH: Right, okay, I do recall that. And then we came back and actually said well, we have other personnel at NRC that -- I remember you stating what about transportation events or something like that and we came back and said well, actually, we have other personnel at NRC that looks at that. So we don't really need to go in that direction. So I think this is kind of a -- it wound up being a no never mind kind of item.

MR. ESSIG: Let me just clarify one point that is that we have a continuing need from the Committee to assist us in the review of events to identify generic issues. That's a very valuable input

by the Committee. And I think the point that was made yesterday was that if we strictly give you just the NMED summaries, that the data in there are insufficient and although the references are listed sometimes getting into Adams and other ways is maybe not the most efficient use of members' time. And I think we agreed yesterday to take an action that when tasked you to do that, we material we provide to you when we do that review will give you the background documentation beyond that paragraph summary that is in NMED to facilitate the review.

MS. McINTOSH: The next action item on the list has to do with another item that was discussed today and not finalized, but it addresses this. The ACMUI subcommittee was to hold some teleconferences to discuss updating the medical event criteria definition and that was done on a couple of occasions. And as a result of that we have the subcommittee's report that the ACMUI voted on and so the staff will have that information to process once we get the transcript back and we can address it more specifically. But a couple of action items that came out of that, I believe Dr. Nag is to e-mail some slides to the entire Committee.

MEMBER NAG: Yes.

MS. McINTOSH: And then the ACMUI will

consult with professional societies regarding an attempt to address egregious behavior on the part of some practitioners who might do something outside the intent of the regulations. I believe an action item was that the ACMUI will consult with professional societies to see if they can help address some language that will sort of minimize egregious behavior, something to that effect.

MEMBER WILLIAMSON: I don't think that was the -- we basically voted on two of three of the less controversial points that were in the report and approved them. I think that the bottom line is just the work is unfinished and we need to keep meeting to do that. We have some ideas on how to proceed that we're going to sit down and go back at it and try to express our concepts more in ordinary language and leave it to you, the experts, to translate them into rule language and then come back. I think that will help facilitate the communication among us in the agreement.

My impression is that this is not ready to be closed out and that I suppose we could ask the Chairman if it would be appropriate for us to continue our efforts meeting via a conference call, perhaps with some additional consultants to help us.

CHAIRMAN MALMUD: That's a recommendation, the Chairman accepts the recommendation.

MEMBER WILLIAMSON: And we continue and try to have a report available with better defined and less controversy within the subcommittee as we -- at least conceptual definition of what medical events should be.

MS. McINTOSH: Okay, if that's no longer an action item of the Committee, I can certainly cross that out.

The last action item that I recall in association with this topic is the ACMUI believes it may be worthwhile for the NRC staff to explore creating some sort of generic communication to define what the end of the procedure is.

MEMBER WILLIAMSON: That I believe was not approved.

MS. McINTOSH: This is an action item. These are not recommendations.

MEMBER WILLIAMSON: Okay.

MS. McINTOSH: The one that I just named, about going to professional societies, that was also an action item. It wasn't a recommendation that was voted on.

Am I correct there?

MEMBER WILLIAMSON: What's the difference between an action item and a recommendation that's voted on?

MS. McINTOSH: A recommendation, you are formally giving us advice on something and asking us to go forward and give you a response on that advice.

An action item is just a task that's being agreed upon. There's no formal, legal implications associated with an action item.

MEMBER WILLIAMSON: Okay, I stand corrected. I was thinking action item is something we had voted on and achieved consensus on.

MS. McINTOSH: Can I then take that to mean that the previous action item that I stated with regard to consulting professional societies is that still an action item of the Committee?

MEMBER VETTER: I don't think we agreed to formally consult with societies, did we? We agreed to consult with colleagues in other societies, so we would be doing that more or less on an informal basis.

MS. McINTOSH: So it may be better to restructure this to say the ACMUI will simply consult with colleagues. Okay.

MEMBER NAG: I don't know whether this was an action item or not, but we had asked to have the

meetings or at least the dates agreed upon well in advance like six months to a year. I don't know whether it's a formal recommendation or action item or what, if it is not, I'd like to make that an action item.

MS. McINTOSH: Can you repeat that, please?

MEMBER NAG: The NRC Staff require well in advance, in parenthesis, six months to one year, the dates for future NRC meetings.

MS. McINTOSH: Okay. That's actually the next thing on the list. We always at the conclusion of every meeting try to at least establish the meeting date for the next meeting. It may be -- it's very difficult to go out beyond the next meeting date because we never know. It's just difficult. We don't know -- it's difficult to project much further out than six months.

MEMBER NAG: In most NRC meetings that I am invited to, usually had the dates one year and sometimes as much as two years in advance, but this being a smaller meeting, I think six months is not unreasonable. The thought behind that, if you make it much smaller than six months you either have to cancel some other appointments or you have to cancel this

one. I think minimum six months, if not more.

MS. McINTOSH: Okay, well, let's try to establish the next meeting date in October. It looks like basically the third week of October is the best week to go with.

MEMBER DIAMOND: When is that?

MEMBER NAG: The third week of October is national meeting for the Radiation Oncology Society.

MEMBER DIAMOND: What's the date of ASTRO?

MS. McINTOSH: The ASTRO meets -- I'm sorry, do you have that?

MEMBER NAG: Yes, it is 16th through 20th of October.

MS. McINTOSH: So the week following that week looks like the best week either Tuesday, Wednesday, Wednesday, Thursday.

MEMBER NAG: That's the last week of October.

MS. McINTOSH: Yes.

MEMBER WILLIAMSON: Could we encourage you, Angela to send a confirmation of the final dates, as soon as possible to all of us?

MS. McINTOSH: What we would like to do is try to confirm them now --

MEMBER WILLIAMSON: I don't have my

calendar here. It's really difficult for me to -- I don't have anything, no.

MS. McINTOSH: But we're looking at --

MEMBER DIAMOND: The week of October 24th? It's okay with me right now.

MS. McINTOSH: So right now we can say October 25th and 26th or 26th and 27th?

MEMBER WILLIAMSON: I have no idea without my calendar.

MS. McINTOSH: So what needs to be done next is that -- let's just say for now, let's go with October 25th and 26th and if that doesn't work, then we'll just try the 26th and the 27th.

If that doesn't work, then we're going to have to push it to November. With Thanksgiving and all, it's more difficult.

That's basically it for me.

CHAIRMAN MALMUD: That completes Angela's report. Is there anything else anyone wants to discuss before we adjourn the meeting?

Sally?

MEMBER SCHWARZ: I just wanted to ask Angela, is the room available, those days, do you know?

MS. McINTOSH: It's too far to project

that the room will be available. We will do what we always do. We will put in the request.

MEMBER SCHWARZ: Do you want people to let you know if this is acceptable for them?

MS. McINTOSH: Right, we're going to go with the first suggested dates of the 25th and the 26th and if everyone -- of course, I can follow up with an e-mail, but if everyone can talk away with the knowledge that we're trying for the 25th and the 26th, check your calendars, make sure that there's not a conflict. If there's any conflicts, then we're going to automatically try for the 26th and 27th.

MEMBER WILLIAMSON: Could you send an e-mail because I think it will be helpful.

MS. McINTOSH: Yes, of course.

MEMBER NAG: Now that we have both the NRC building and possibly the hotel for the meeting, if we contact the room over at the NRC building and -- can we use this hotel? The only thing we need to know is the date and if the location -- I don't mind whether NRC or here.

DR. MILLER: If we get the date established which I think is most important than what we don't want to do is change the date. So we have three options. We have getting the ACRS/ACNW meeting

room, getting the NRC auditorium where we held one meeting, or getting this facility, if it isn't booked. Okay? I guess as long as we agree upon the dates, I think we can accommodate getting a meeting room.

MS. McINTOSH: Yes. We can find a venue, if we can just agree upon the dates.

DR. MILLER: I think it's more important to lock in the dates at this point.

CHAIRMAN MALMUD: Yes.

DR. MILLER: I mean we had some disruptions here with the background noise and the microphones, but other than that, I thought it was a reasonable place.

MEMBER EGGLI: You should have made a special request for the song fest going on across the way.

DR. MILLER: Yes, we didn't pay for the entertainment, so it was great.

MR. ESSIG: And I would add, even if this is available, I would consider it to be a last resort, simply because this cost us $5,000. The other rooms we get for nothing, believe it or not, 5 grand.

MEMBER NAG: The other Marriott North has been open, it's possible to have a tentative booking for everyone there and anyone who doesn't like it can

cancel.

MR. ESSIG: The problem is if we reserve a block of rooms, I've never been convinced that this Committee is willing to stay at the same hotel because you all have your own preferences. I know, Ralph, you've suggested that before, that we have a block of rooms. We can do that on a voluntary basis, and the only thing I have to say for it is that we don't get booked for any -- billed for any rooms that we don't use.

MEMBER NAG: But back before when we didn't have any convenient hotel, now that we have a convenient hotel across the street, I think that's different and any other place you can have it held for one month or something and anyone who doesn't want it can cancel it.

DR. MILLER: I'd have to pursue whether we can do that through our travel.

MEMBER LIETO: I was just going to say if we could set it up with Carlson Travel and let them just handle all of the arrangements, that way it's not something everybody is beating Angela up or Tom about.

DR. MILLER: Let's pursue whether or not it can be done. Again, what Tom said, we have to protect against somebody not being able to make the

meeting and we've got a commitment to have that room booked.

MEMBER LIETO: If you just have it set up such that by X number of weeks beforehand, after that date, you're on your own. If they don't book it, you release it.

CHAIRMAN MALMUD: What happens if you book it and have to cancel?

MEMBER SULEIMAN: I think Marriott, the last I remember, Marriott has honored the federal per diem. Did anybody stay here?

MEMBER EGGLI: I did.

MR. ESSIG: And did you get it for federal per diem?

MEMBER EGGLI: They honor Government per diem. There were no rooms left, so I opted to pay the delta myself.

DR. MILLER: There were no rooms left to Government per diem?

MEMBER EGGLI: Yes.

DR. MILLER: But they were willing to offer you a room at a higher rate?

MEMBER EGGLI: Sure. They all did.

MEMBER WILLIAMSON: What's the per diem?

MEMBER NAG: $153.

MEMBER WILLIAMSON: I had to pay $191 and I just had my institution make up the difference so I didn't have a problem there. But rarely have they been able to get into a hotel for the cheaper rate. It's very difficult.

MR. ESSIG: But sometimes Carlson is able to do that and I don't --

DR. MILLER: We may not have a big enough number of people for them to be able to do it. Like I know --

MEMBER LIETO: Unless everybody is doing it on their own as opposed to having 12 -- probably 12 people doing it, it might be a little bit -- you might have a little bit of leverage that way.

MR. ESSIG: We can certainly talk with Carlson people. They make your flight arrangements or other travel arrangements. They can make the hotel part of the same deal.

MS. McINTOSH: One of the advantages of agreeing upon a meeting date this far in advance is that people do know when we're going to have a meeting and can therefore book rooms now.

So the key to getting a room is to not wait too late to book it and if we had -- once we've confirmed the date which shouldn't take too long, the

next step then would be to book the room.

MEMBER NAG: And that is what I had done the last time. It was April 11th and 12th. I had my room at the $153 rate and then we canceled it. When I canceled that rate and gave the new dates, it was not available.

So have to keep the date once we make the dates.

CHAIRMAN MALMUD: Well, if it's any other conciliation, all other hotel rooms failed. The Ramada Inn will always take you and the nice thing about the Ramada Inn you enjoy very much getting up early and getting out of there.

(Laughter.)

I hope that's not for the record. If there's no other serious business, we will adjourn the meeting.

Thank you all. Thank you all.

(Whereupon, at 4:44 p.m., the meeting was concluded.)