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NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

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TELECONFERENCE

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TUESDAY,

FEBRUARY 7, 2012

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The teleconference convened at 12:00 p.m. Eastern Standard Time, LEON S. MALMUD, M.D., Chairman, presiding.

MEMBERS PRESENT:

LEON S. MALMUD, M.D., Chair

BRUCE THOMADSEN, Ph.D., Vice Chair

DARICE BAILEY, Non-voting Member

MILTON GUIBERTEAU, M.D., Member

SUE LANGHORST, Ph.D., Member

STEVE MATTMULLER, Member

CHRISTOPHER J. PALESTRO, M.D., Member

MEMBERS PRESENT (Continued):

JOHN SUH, M.D., Member

ORHAN SULEIMAN, Ph.D., Member

LAURA WEIL, Member

JAMES WELSH, Ph.D., Member

PAT ZANZONICO, Ph.D., Member

NRC STAFF PRESENT:

MICHAEL FULLER, Designated Federal Officer

ASHLEY COCKERHAM, Alternate Designated Federal Officer

BRIAN McDERMOTT, Director, Division of Materials Safety and State Agreements

PAM HENDERSON, Acting Deputy Division Director, Division of Materials Safety and State Agreements

MARIA ARRIBAS-COLON

SUSAN CHIDAKEL

SAID DAIBES, Ph.D.

DONNA BETH HOWE, Ph.D.

GRETCHEN RIVERA-CAPELLA

RONALD E. ZELAC, Ph.D.

SANDY GABRIEL, Region I

PATTY PELKE, Region III

LIZETTE ROLDAN-OTERO, Region IV

LATISCHA HANSON, Region IV

ALSO PRESENT:

KEITH BROWN, University of Pennsylvania
KAREN COLUCCI, Albert Einstein Healthcare
ROBERT DANSEREAU, New York State Department of Health
WILLIAM DAVIDSON, University of Pennsylvania
RONALD ENNIS, American Society of Radiation Oncology
LYNNE FAIROBENT, American Association of Physicists in Medicine
PETER GOYER, Albert Einstein Healthcare Network
THOMAS HUSTON, Veterans Health Administration
DENNIS KEHOE, Jeppensen Radiation Oncology Center
RALPH LIETO, St. Joseph Mercy Hospital
JANETTE MERRILL, Society of Nuclear Medicine
SUBIR NAG, Kaiser Permanente
MICHAEL PETERS, American College of Radiology
BRADLEY PRESTIDGE, Society of Nuclear Medicine
JOSEPH RODGERS, Theragenics Corporation
GLORIA ROMANELLI, American College of Radiology
KAREN SHEEHAN, Fox Chase Cancer Center
MICHAEL SHEETZ, University of Pittsburgh
ERIC SOLTYCKI, Albert Einstein Healthcare Network

CINDY TOMLINSON, American Society for Radiation Oncology

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

(12:02 p.m.)

MR. FULLER: Good afternoon. This is Mike Fuller. We'll go ahead and get started. I have some prepared remarks here for this call.

As the designated federal officer for this meeting, I am pleased to welcome you to this public meeting of the Advisory Committee for the Medical Uses of Isotopes.

My name is Mike Fuller. I am the team leader of the medical radiation safety team in the Radioactive Materials Safety Branch. And I have been designated as the federal officer for this Advisory Committee in accordance with 10 CFR Part 7.11. Present today as the alternate designated federal officer is Ashley Cockerham. She is the ACMUI Coordinator.

This is an announced meeting of the Committee. It is being held in accordance with the rules and regulations of the Federal Advisory Committee Act and the Nuclear Regulatory Commission. The meeting was announced in the February 13th, 2012 edition of the Federal Register. I'm sorry. That must be January 13th. Forgive me. That was, again, in the Federal Register, volume 77, page 2098.

The function of the Committee is to advise the staff on issues and questions that arise on the medical use of byproduct material.The Committee provides counsel to the staff but does not determine or direct the actual decisions of the staff or the Commission. The NRC solicits the views of the Committee and values their opinions.

I request that, whenever possible, we try to reach a consensus on the procedural issue that we will discuss today, but I also recognize that there may be minority or dissenting opinions. If you have such opinions, please allow them to be read into the record.

At this point, I would like to perform a roll call of the ACMUI membership that is participating today. First, Dr. Malmud?

CHAIR MALMUD: Present.

MR. FULLER: Dr. Thomadsen?

VICE CHAIR THOMADSEN: Present.

MR. FULLER: Ms. Darice Bailey?

MEMBER BAILEY: Present.

MR. FULLER: Dr. Mickey Guiberteau?

MEMBER GUIBERTEAU: Present.

MR. FULLER: Dr. Sue Langhorst?

(No response.)

MS. COCKERHAM: I did hear her say she was on the line earlier.

MR. FULLER: I thought I did, too.

Dr. Langhorst, are you on the line?

MEMBER LANGHORST: I'm sorry. I'm here. Can you hear me?

MR. FULLER: Yes. We can hear you now.

MEMBER LANGHORST: Okay.

MR. FULLER: Mr. Steve Mattmuller?

MEMBER MATTMULLER: Present.

MR. FULLER: Dr. Christopher Palestro?

MEMBER PALESTRO: Present.

MR. FULLER: Dr. John Suh?

MEMBER SUH: Present.

MR. FULLER: Dr. Orhan Suleiman?

MEMBER SULEIMAN: Present.

MR. FULLER: Dr. William Van Decker?

(No response.)

MR. FULLER: Ms. Laura Weil?

CHAIR MALMUD: I heard Laura sign on earlier.

MEMBER WEIL: I'm here.

MR. FULLER: Okay. Dr. James Welsh?

MEMBER WELSH: Here.

MR. FULLER: Dr. Pat Zanzonico?

MEMBER ZANZONICO: Present.

MR. FULLER: Okay. I would, first of all, note that a quorum has been established and met. I would also note that Ms. Bailey does not have voting privileges at this time, but she will listen and speak on behalf of the Agreement States.

Now I will ask NRC staff members who are present to identify themselves. I'll start with individuals in the room here at NRC headquarters, and then I will go out to the phone to each of the NRC regions and other staff that we know are on the line. Okay.

So, again, my name is Mike Fuller. And then?

DR. HOWE: Dr. Donna Beth Howe, medical team.

MS. CHIDAKEL: Susan Chidakel with the Office of General Counsel.

MS. HENDERSON: Pam Henderson, FSME.

MR. MCDERMOTT: Brian McDermott, FSME.

DR. DAIBES: Said Daibes, FSME.

MS. RIVERA-CAPELLA: Gretchen Rivera-Capella, medical team.

MR. FULLER: Okay. And then also do we have members -- I'm sorry -- NRC headquarters employees who

are on the phone?

MS. ARRIBAS-COLON: Yes. Maria Arribas-Colon.

DR. ZELAC: Ronald Zelac, medical team.

MS. COCKERHAM: Ashley Cockerham, also with the medical team.

MR. FULLER: Okay. We will go out to the regions, then. Region I?

MS. GABRIEL: Sandy Gabriel.

MR. FULLER: Anyone else from Region I?

(No response.)

MR. FULLER: Okay. Region III?

MS. PELKE: Patty Pelke.

MR. FULLER: Okay. Region IV?

MS. ROLDAN-OTERO: Lizette Roldan-Otero.

MS. Hanson: Latischa Hanson, DNMS Inspections.

MR. FULLER: Okay. At this time I would like to ask Ashley Cockerham to call the roll for those individuals, members of the public, who have indicated that they plan to participate.

MS. COCKERHAM: Okay. First we have Dave Adler?

(No response.)

MS. COCKERHAM: Dr. Keith Brown?

DR. BROWN: Here.

MS. COCKERHAM: Karen Colucci?

MS. COLUCCI: Present.

MS. COCKERHAM: Robert Dansereau?

MR. DANSEREAU: Here.

MS. COCKERHAM: Will Davidson?

MR. DAVIDSON: Here.

MS. COCKERHAM: Dr. Ronald Ennis?

DR. ENNIS: Here.

MS. COCKERHAM: Lynne Fairobent?

MS. FAIROBENT: Here.

MS. COCKERHAM: Joseph Goldstein?

(No response.)

MS. COCKERHAM: Peter Goyer?

MS. COLUCCI: He will be attending shortly.

MS. COCKERHAM: Okay. Thank you.

Dr. Michael Hagan?

(No response.)

MS. COCKERHAM: Kathi Haldeman?

(No response.)

MS. COCKERHAM: Dr. Thomas Huston?

DR. HUSTON: Present.

MS. COCKERHAM: Mary Ellen Jafari?

(No response.)

MS. COCKERHAM: Dennis Kehoe?

MR. KEHOE: Here.

MS. COCKERHAM: Ralph Lieto?

MR. LIETO: Present.

MS. COCKERHAM: Janette Merrill?

MS. MERRILL: Present.

MS. COCKERHAM: Michael Peters?

MR. PETERS: Here.

MS. COCKERHAM: Dr. Bradley Prestidge?

DR. PRESTIDGE: Here.

MS. COCKERHAM: Joe Rodgers?

MR. RODGERS: Present.

MS. COCKERHAM: Gloria Romanelli?

MS. ROMANELLI: Here.

MS. COCKERHAM: Karen Sheehan?

MS. SHEEHAN: Here.

MS. COCKERHAM: Michael Sheetz?

MR. SHEETZ: Present.

MS. COCKERHAM: Eric Soltycki?

MR. SOLTYCKI: Here.

MS. COCKERHAM: Did I get close on that one?

MR. SOLTYCKI: Very close.

MS. COCKERHAM: Cindy Tomlinson?

MS. TOMLINSON: I'm here.

MS. COCKERHAM: Boris Tsenov?

(No response.)

MS. COCKERHAM: Is there anyone else I did not identify?

DR. NAG: Subir Nag.

MS. COCKERHAM: Oh. Hi, Dr. Nag.

MS. SHEEHAN: Hi. This is Karen Sheehan. I am here.

MS. COCKERHAM: Thanks, Karen. Okay. That's it for me, Mike.

MR. FULLER: Okay. Thank you, Ashley.

Following a discussion of the scheduled item, the ACMUI Chairman, Dr. Leon Malmud, at his option, may entertain comments or questions from members of the public who are participating with us today.

I would also like to add that the handouts and agenda for this meeting are available on NRC's public website.

At this point I would like to turn the meeting over to Brian McDermott. Brian is the Director of the Division of Material Safety and State Agreements here at NRC.

MR. McDERMOTT: Thanks, Mike.

I would like to welcome the ACMUI to this teleconference. At today's conference, we will be

discussing the ACMUI's Subcommittee report on permanent implant brachytherapy medical reporting.

This is an important topic to the NRC as well as to the medical community. And I would like to thank the Committee for their continued hard work in this area. The staff is looking forward to the ACMUI finalizing its recommendations.

I would also like to take this opportunity to welcome Ms. Darice Bailey to the Committee. Ms. Bailey was selected as the State Government Representative in December. She is currently a health physicist for Texas' Department of State Health Services, where she is Manager of the Radioactive Materials Group.

Finally, I would like to just note that the staff is looking forward to meeting with the ACMUI members in person at our headquarters here in Rockville, Maryland on April 16th and 17th.

At this point I would like to turn the meeting back over to Dr. Malmud.

CHAIR MALMUD: Thank you.

This is Leon Malmud. In the interest of time, I would like to turn the meeting over immediately to the Chairman of the Subcommittee: Dr. Welsh.

MEMBER WELSH: Good morning, everyone. The purpose of today's call is to discuss yet another revision of the Permanent Implant Brachytherapy Subcommittee so-called final report.

As most of you are aware, the --

THE REPORTER: I'm sorry to interrupt. This is the Court Reporter. Dr. Welsh here is sort of fading in and out.

MEMBER WELSH: Okay. Is that any better?

MS. COCKERHAM: This is Ashley. If everyone else could press *6 to mute their lines who is not speaking? Thank you.

MEMBER WELSH: Okay. Can you hear me?

THE REPORTER: I can. Please continue.

MEMBER WELSH: The Subcommittee has had a number of revisions to the reports that date back several years. For example, there was one in 2008 that contained much of what is going to be discussed today. There was another one in 2010. Most recently there was one in late 2011, which was a significant change from previous suggestions contained in the previous reports.

In the interim between that October-December Subcommittee report and the report that is being discussed today, there were a number of

communications from experienced practitioners, professional organizations, and others regarding the content within our 2011 report. And some have voiced the opinion that there would be some practical challenges to implementation of the 2011 suggestions.

Having said that, I believe that the 2011 suggested definition for medical event was quite good. I think that the one that we have now that was modified in January 2012 is also quite good. I do think that when it comes to practical challenges and some specific content of the report; for example, use or not use of D-90, that in my opinion, the 2012 version is slightly superior.

But before I go any further, I should mention that the Subcommittee, although it was only a handful of people, four people, there was not a unanimous decision. There was not a consensus in our recommendation. And there is a very strong opposition to some of the content contained within. And it is added as an addendum to this Subcommittee report and titled "Minority Report." And I would ask the Subcommittee member who led that particular section to speak up when there are controversies that we need to be reminded of.

Basically, there are a couple of

significant differences between the late 2011 versus the 2012 report. And the principal difference is that in the latest rendition, the 2012 Subcommittee recommendations, we do not advocate use of D-90 in any form or fashion when it comes to medical event definition.

And I will say that this is because after many years of arguing against using D-90 or dose or for prostate brachytherapy as a specific example, I and many others have come to the conclusion that dose is not an appropriate parameter to use when it comes to the definition of the medical event, even if it is being used, as in the 2011 version, to basically screen out possible medical events and because of the Boolean algebra prevent something being called a medical event. I personally and others on the Subcommittee were not in favor of the use of D-90.

Another change to the Subcommittee report is the omission of the octant concept. The octant concept was introduced in the late 2011 version. And it's an elegant concept, which logically makes a lot of sense, but some members felt that this could be very difficult to implement on a daily basis for regulatory purposes.

And the third difference between the late

2011 and the 2012 version is the inclusion of the attestation by the authorized user in the written directive completion.

Both versions include the written directive completion. The latest version includes an attestation by the authorized user in this written directive completion that specifically mentions that the seed distribution is in accordance with the plan. That is a key point that it is in accordance with the plan and, therefore, can't be objectively compared to that plan.

So, with that introduction, I will bring it back to Dr. Malmud.

CHAIR MALMUD: Thank you.

Are you able to hear me? Are you able to hear me?

DR. NAG: We are muted. I have to unmute before we can say, "Yes, we can hear you."

CHAIR MALMUD: Thank you.

We have heard the report of the Chairman and the background for the recommendations. The item is now open for discussion.

I believe you all have received or have access to the material that was sent out, which is entitled "The Advisory Committee on Medical Isotopes

Permanent Implant Brachytherapy Final Report, Modified January 2012." And the item is open for discussion. Is there a --

MEMBER ZANZONICO: Yes. This is Pat Zanzonico.

I have a question with respect to the attestation required. As it's stated in the draft report, the authorized user is attesting to the fact that the actual seed placement and so forth was done according to the pre-op plan. But shouldn't there be a provision where the physician can state that they purposely deviated from the pre-op plan because of unforeseen circumstances interoperatively or is there some other provision that I overlooked in the draft report to account for that?

CHAIR MALMUD: Dr. Zanzonico's question is to Dr. Welsh or any member of the Committee. Dr. Welsh?

MEMBER WELSH: This is Jim Welsh. I could attempt to answer that for Dr. Zanzonico.

The wording in the current draft states that "The authorized user should provide a statement in this written directive completion attesting that the permanently implanted sources had been placed in accordance with the planned distribution."

So it does not specifically say that we must be using a pre-plan or that we're using a plan that was generated before the procedure or whether it was an intraoperatively, actively modified, on-the-fly kind of plan. It just says "planned distribution" to keep it general.

So that it does, in essence, attempt to answer your question or anticipate your question so that it is not specifically a pre-plan that we are talking about. We are talking about the final planned distribution. And I suppose if there is objection to the way it is worded, we should say, "in accordance with the final planned distribution."

DR. NAG: This is Dr. Nag. I heartily agree with your revised statement. And I think your revised statement would make it much more clear.

CHAIR MALMUD: Thank you, Dr. Welsh and Dr. Nag.

Dr. Welsh, are you recognizing that the word "final" be placed in there as a modifier?

MEMBER WELSH: I suppose if others were as concerned as Dr. Zanzonico is, that putting the word "final" planned distribution would be acceptable and is appropriate.

CHAIR MALMUD: This is --

MEMBER WELSH: I'll ask others on the Subcommittee if they have any objections or feelings on this, but I think that it does clarify things, as Dr. Zanzonico has pointed out.

CHAIR MALMUD: This is Malmud. Dr. Langhorst, Dr. Suh, Dr. Thomadsen, do you agree?

VICE CHAIR THOMADSEN: This is Thomadsen. I would abstain.

CHAIR MALMUD: Dr. Thomadsen abstains. Dr. Langhorst, Dr. Suh?

MEMBER SUH: This is Dr. John Suh. I am okay with the addition of the word "final."

CHAIR MALMUD: Thank you.

Dr. Langhorst?

MEMBER LANGHORST: This is Sue Langhorst. I think the question that Pat was asking was whether the authorized user could also document any changes that he or she had to make during this surgical implant.

And I agree that the authorized user should be able to make those changes as if there is a -- surgical implant in medical and other bits of challenges make it important that that authorized user be able to make changes during that procedure.

I am not sure if adding the word "final" right there is the right way to do that, but I do

agree with the point that Pat was making.

One thing implicit with all of this is that the authorized user is either doing this procedure or is right there in the operating room helping to direct this procedure. And that is probably something that is subtle in this statement, but I wanted to make sure people understood the intent that the authorized user needed to be present.

MEMBER WELSH: This is Dr. Welsh again. If I might speak, Dr. Malmud?

CHAIR MALMUD: Indeed.

MEMBER WELSH: I would slightly disagree with Dr. Langhorst here and disagree with her interpretation of what Dr. Zanzonico is asking. I guess ultimately we have an easy way of answering this question.

But if you are arguing that we're saying that Dr. Zanzonico's question was regarding documentation changes that need to be made during the operative procedure, I would say that the sentence right before that addresses that specific point.

What happens there, it says, "Unusual aspects of the procedure, including patient-related limitations, should be documented in this written directive completion."

So if there were any changes I believe that could be made on the fly, any slight adjustments, any challenges because of patient anatomy, they would be documented within this written directive completion. And then there would probably be something saying that because of these anatomical changes, the plan had to be adjusted slightly.

And so the final plan is that the authorized user should be attesting to. So I don't think that adding the word "final" is going to affect this concept in any way. And, for that reason, I would remain in favor of inserting it.

MEMBER SULEIMAN: This is Orhan Suleiman. Can I ask a question?

CHAIR MALMUD: Yes, please, Dr. Suleiman.

MEMBER SULEIMAN: Okay. Is that last sentence there really necessary? You have already stated -- I'm using the last phase of the procedure, including patients -- that patients should be documented in this written directive completion. What value does the last sentence add?

MEMBER WELSH: May I ask which sentence specifically?

MEMBER SULEIMAN: The sentence that says, "The authorized user should provide a statement in

this written directive completion attesting that the permanently implanted sources had been placed in accordance with the planned distribution."

MEMBER WELSH: I can take a stab at that. This is Jim Welsh. I think that it is absolutely imperative that such a statement be included because this is the line that holds the authorized user responsible for the final seed distribution. And this is one way that we are attempting to deal with the seed distribution problem that has been argued for the past several years.

For example, if all of the seeds are in one line or if all of the seeds are bunched in one spot, such a bizarre situation could fly under the radar of many of the previous attempts at a medical event definition. And that is why, in part, the octant concept evolved, but because the octant concept has some limitations or inherent difficulties in my personal opinion -- and Dr. Thomadsen has a different perspective -- the alternative is this statement of attestation saying that the seeds have been placed in accordance to the computerized plan. And that specific statement I believe is important.

MEMBER SULEIMAN: That confuses me. So what if it deviated from the plan? Then don't they explain

that? And isn't that what's said in the preceding sentence?

MEMBER WELSH: It is. So if there is a very challenging situation, the plan would have to be modified. And sometimes anatomical considerations or technical limitations will preclude achieving a seed distribution that is in exact compliance with the called-for seed distribution on the computer. But this is where I think that the two sentences, one stating additional circumstances that were encountered, technically or anatomically; and the other attesting that the final distribution was placed as close as humanly possible to the final desired plan.

MEMBER SULEIMAN: Okay. So those last two sentences really mean you're going to validate or attest that, in fact, the procedure went as planned or it deviated and these are the reasons why it deviated? That's really what you want to say in those two sentences.

MEMBER WELSH: So you make a positive statement that everything went as planned or it didn't and this is why. And that is -- I would consider that all part of the practice of medicine.

DR. NAG: This is Dr. Nag. Can I say a couple of words?

CHAIR MALMUD: Please?

DR. NAG: Okay. At the Asheville meeting, where we had lots of experienced users who were doing this, we came up with this because the subnormal distribution or distribution of seed not in accordance with a pre-plan would be used for two reasons: one, that you purposely deviated from the plan, either because there was bone or some other anatomical structure preventing you from putting it there; -- and that's the reason for the first sentence -- or that because of error or because of something that you did not foresee and there was a misplacement. So we wanted to clarify the two differences.

If it's a misplacement, then it could be a medical event; whereas, if it was done purposely because of certain reasons the authorized user wanted to do, then it would not be a medical event. So that was the reason for the two sentences. And if the authorized user said that this was the way he wanted to do it, then it's quite different from yes, he wanted to do it that way, but then, you know, by mistake, they put the needle in the wrong place.

CHAIR MALMUD: Thank you.

Other questions regarding addition of the word to the existing sentences in section D?

DR. NAG: This is Dr. Nag. I have a couple of comments. Since I had been involved not only while I was at the ACMUI, but also in the actual committees, first of all, I wish to congratulate the Subcommittee on their revised recommendations.

I heartily agree that the D-90 concept cannot be used as a regulatory means. The D-90 concept is only to be used for seeing the prognosis and so on. I heartily agree with that.

I also agree with taking the octant concept out. The concept is very good for theoretical reasons. However, even if you use the octant concept, you could bunch up all the seed in the center, right in the urethra, and provided that all of the seeds are in the different octant until it will qualify as the octant, but it will still go up the urethra.

Also, there are many people who do not implant the -- or the organ homogeneously. And in that case, the octant concept would not work.

So one concern I still do have now in the new one is that the intra-target structures, such as the urethra, that those do at least 5 cc at seed 150 percent of that structure exposed dose.

The words I do not like is "the expected dose made on an improved implant dose distribution."

The reason I do not like that is if the expected dose was extremely low, then 150 percent of that extremely low dose is still extremely low. And it's not of any clinical concern, but would be defined as a medical event in this case.

In the urethra, we have come very close to the 100 percent or 150 percent of the prescribed dose. So for the urethra, it may not matter too much. But I'm thinking that this permanent implant -- this rule is really for all permanent implants. And in that case, those are low. And 150 percent of a low amount is still low.

I would like to have that word "expected dose" somehow reworded so that it has some context to the tolerance of that structure. A 150 percent dose is nowhere close to the following of that structure. It's basically not a problem.

And I would like to hear the Subcommittee's response to that.

MEMBER WELSH: Dr. Malmud, this is Jim Welsh. If I could attempt a response?

CHAIR MALMUD: Please do.

MEMBER WELSH: First, I would like to return briefly to our discussion at hand, which was the question of whether or not inserting the word

"final" would be worthwhile. And I continue to believe that, thanks to Dr. Zanzonico's question, that introducing the word "final" may be appropriate.

To answer Dr. Nag's question, I think it's a legitimate point, but I would point out first that the section A.2 regarding normal tissue structures is an a, 2(a) and 2(b). And it's an "or" there, but it is divided into neighboring structures for (a), which would be things such as the bladder or rectum and prostate, which we are all familiar with. And (b) is for intra-target structure. And the only intra-target structure that comes to mind in prostate is the urethra.

I would agree that this section as our recommended definition perhaps could benefit from some modifications, but I don't think that we would have too much difficulty with the current wording in that it is the expected dose based on the approved pre-implant dose distribution.

And, as Dr. Nag has pointed out, the urethra dose is often somewhere around 100 percent of the dose to the PTV, but it would have to exceed 150 percent of the expected dose. And sometimes the expected dose depending on the specifics of the plan for the urethra could be considerably higher if it is

not peripherally loaded, for example, if the seed distribution is relatively uniform the dose to the urethra could be maybe 150 percent of the dose to the perimeter, to the CTV or PTV. And it would have to exceed 150 percent of the expected dose, which, as I said, might be 150 percent of the PTV.

So if we were talking about 200 gray to the urethra, it would have to be 150 percent above that to trigger a medical event.

Having said all of that, I am not strongly opposed to introduction of tolerance, which is, in reality, more important. And the challenge would be tolerance would differ organ to organ, site to site, procedure to procedure. And unless we were going to put in the term "tolerance," rather than "planned, expected dose," we would have some difficulty with this.

"Tolerance," I suppose, could solve the problem, but then we would have to have specific definitions of the tolerance for each individual organ in question. And this becomes a little bit of a regulatory challenge; whereas, 150 percent of the planned dose is much easier to regulate and inspect because it doesn't assume a necessary additional knowledge on the part of the inspector.

DR. NAG: This is Dr. Nag. May I respond?

CHAIR MALMUD: Yes.

DR. NAG: Okay. So I agree to some extent with Dr. Welsh. However, you have to remember a couple of things. Number one, this rule is going to be not only for the prostate, but for any permanent implant.

I have done permanent implant, say, in the liver. In the middle of the liver, you are going to have the inferior vena cava. Now, those that I am giving are quite low, but the tolerance of the inferior vena cava is very high.

I could easily get 200 percent of my expected dose to the vena cava and it wouldn't be a problem. However, by this definition, it would become a problem, number one.

Number two, even in the urethra, -- let's say you are going to make the supply only to the urethra -- the urethra volume, the total volume, at least on the implants that I do, the total volume of the urethra, is nowhere close to five cc. Therefore, having the statement of 5 cc, of a dose to at least 5 cc, is 150 percent, is basically meaningless because unless there is an unusually large or unusually wide urethra, you are not going to come to anywhere close to 5 cc. I hope that was the statement in for

consideration.

So I would suggest that the 150 percent of the expected dose is not what the physicians want to refer to. We would consider it a misadministration of medical event if it related to the tolerance of that dose. Otherwise, I think that, you know, we have to maybe put an "and," that it says a dose exceeded 150 percent of the doctor's expected dose and expected tolerance, or something like that.

I haven't given enough thought as to how that sentence is to be reworded, but it has to be reworded. Otherwise, you are going to have some inappropriate definitions.

Thank you.

DR. ENNIS: This is Ron Ennis. Could I talk?

CHAIR MALMUD: I have a question for clarification. What is the sentence to which you are referring? The proposed sentence or --

DR. NAG: Okay. So this is the sentence in the recommendation, A.2(b).

CHAIR MALMUD: Okay. So you are recommending that that sentence be somehow modified?

DR. NAG: Yes.

CHAIR MALMUD: So we now have -- before we

move on to that sentence, may we first resolve the issue of the addition of the word "final" to the recommendation B, paragraph 1, the last sentence?

Three out of four of the Subcommittee members agreed. One abstained with the insertion of the word "final." As Chair of the Subcommittee, Dr. Welsh, is that acceptable?

MEMBER WELSH: This is Dr. Welsh here. To me, that is acceptable. If three out of the four are in agreement here, it is as good as I can expect on this particular subject because our abstaining member has a very, very different perspective, which I'm sure will be expounded on shortly. So yes, I am comfortable with the addition of that word.

CHAIR MALMUD: May we take that as a motion to this, to add to this recommendation?

(No response.)

CHAIR MALMUD: If so, since the Subcommittee is in favor of the motion three to four, three out of four, is there a second to a member of the Subcommittee?

MEMBER SUH: I second the motion. This is John Suh.

CHAIR MALMUD: Thank you.

And now we have a motion that has been

seconded. It is now open for discussion. And this would give Dr. Thomadsen the opportunity to express the reasons for his abstention if he wishes to do so.

VICE CHAIR THOMADSEN: Hi. I abstained because I am against the attestation altogether.

CHAIR MALMUD: Thank you. Is that all you wish to say?

VICE CHAIR THOMADSEN: On this motion. On this motion, yes.

CHAIR MALMUD: Thank you.

So the motion has been moved and seconded. Any further discussion of the motion?

(No response.)

CHAIR MALMUD: There seems to be no further discussion of the motion. May we move on the motion? All in favor of this motion, which is the addition of the word "final" to the last sentence of recommendation B, paragraph 1? All in favor?

(Whereupon, there was a chorus of "Ayes.")

CHAIR MALMUD: Any against?

(No response.)

CHAIR MALMUD: Any abstentions?

VICE CHAIR THOMADSEN: This is Thomadsen. I abstain.

CHAIR MALMUD: One abstention. So the

motion carries.

Now, if we may, we will move on to another item which has been raised. And that is an item raised by Dr. Nag. Am I correct, Dr. Nag?

DR. NAG: Yes.

CHAIR MALMUD: Would you care to express your concern and recommendations?

DR. NAG: I had already expressed my concern. My recommendation is that sentence be modified or eliminated. And that was the intent of its structure, such as the urethra and the prostate implant as an example, but those 2 at least 5 cc contiguously had received 150 percent of that structure's expected doses on approved pre-implant dose distribution.

As I had mentioned previously, you know, just now, that sentence will not apply to the prostate because the urethra volume is not five cc less than that. And, number two, it becomes difficult or dangerous when it applies to other structures where the normal tissue tolerance may be way higher than what the expected dose to that normal tissue would be. So that sentence to me does not have -- I have great concern for that sentence,

DR. ENNIS: This is Ron Ennis. Could I

speak?

CHAIR MALMUD: Please do.

DR. ENNIS: Thank you.

So I share with Dr. Nag some of the concerns and had a potential alternative suggestion. In particular, the volume issue, five cc is essentially irrelevant when it comes to the urethra, which is generally only about a cc in volume. So there would never be a medical event on that basis.

And also having in mind, as Dr. Nag is suggesting, that we want this to be as universal as possible, but also needed to work and not be overly cumbersome with, I think, a different dose for every possible tissue in the body would really be unworkable. Another possibility would be that the medical event be considered that if we define it by a proportion of the normal tissue that we're discussing so that the highest dose would be, let's say, a 5 percent, if 5 percent of the normal tissue got a dose, more than 250 percent of its prescribed dose, that that I think would be something that could be uniformly considered a medical event, would be a simple thing to apply. I think it could apply across all normal tissues in a uniform way.

I think it would avoid Dr. Nag's concern

about higher than prescribed doses at the low end being called a clinical event because this is so much higher than the prescribed events that it would be unlikely that it would trigger a medical event without it being of some clinical relevance as well.

So I would propose that as a potential alternative definition.

CHAIR MALMUD: Thank you, Dr. Ennis.

DR. NAG: This is Dr. Nag. My suggestion would be to eliminate that sentence altogether because, even with 250 percent and if you're taking to test a small, you know, five percent of that, the inhomogeneity within a structure that is to be implanted is not something that is within the jurisdiction of the NRC. It is within the jurisdiction -- it is medical, and it is not in the jurisdiction of NRC to define actually what shows in the implant.

And I would highly suggest that the NRC refrain from trying to dictate what should be given to every cell within the implanted tissue. Outside the implanted tissue, you do not want to harm normal tissue but not within the target volume.

CHAIR MALMUD: Thank you, Dr. Nag. Are you recommending, therefore, that under recommendations A, subheading 2 for normal tissue structures, that only

part B remain and that part A be struck?

DR. NAG: No, no, no. The other way around. Part A remains. Part B is struck out because if the target -- how that dose is distributed within the target is not really within NRC's jurisdiction.

CHAIR MALMUD: Thank you for that clarification.

So Dr. Nag's recommendation is that under capital A, part 2, that we leave only one section in.

DR. NAG: That part A remains. Part B, even if it were to remain the way it is, has absolutely no meaning because the urethra will never be five cc.

We have tried to think of different ways of trying to regulate something within the volume. And that is almost impossible to do and not have some other unintended consequence if you are trying to manipulate the dose within a target.

CHAIR MALMUD: Thank you, Dr. Nag.

So we have two opinions. One is Dr. Nag's that part B be struck. The other is Dr. Ennis' suggestion of the 5 percent more than 250 percent.

Dr. Ennis, do you wish to comment?

DR. ENNIS: So I think that if we are trying to define medical event as something that is, you know, egregious and a potential public harm, then

the structures, even within the target, are important. And some definition of a medical event, therefore, makes sense.

It is always going to be a bit of a challenge, I think. And it is somewhat imperfect. I think we could quibble a little bit about the percent volume and the percent prescribed dose above thresholds. And maybe 10 percent of the volume and 300 percent would make Dr. Nag a little more comfortable. I certainly don't feel strongly about the exact parameters.

I think the five percent is a good one that would really work across the board. A little bit of wiggle on that, as I just mentioned, I think would be acceptable. I would be less comfortable with the definition that excluded normal tissues within the target from any possibility of being a medical event. I don't think that that is logical.

I think the normal tissues in the middle of the target are crucial to make sure they are protected. And obviously we need, as Dr. Nag has alluded, some flexibility. And we have some flexibility with that. It can't be a rigorous definition that is at 100 percent and nothing above but within some reasonable guidelines, allowing for

dose inhomogeneity of brachytherapy, I think that something like this would be reasonable.

DR. NAG: This is Dr. Nag.

CHAIR MALMUD: Okay. Dr. --

DR. NAG: We can only put a limitation if it is eliminated with the tolerance of that normal tissue. You cannot have a certain percentage of that expected dose to that tissue if it is not related to the tolerance of that tissue. If we make it 300 percent, 400 percent, if it is nowhere close to the tolerance of that tissue, the percentage has no meaning, 300 percent or 400 percent. If that is within a target, within something you want to implant, then the tolerance -- it has to be related to the tolerance. Otherwise, a percentage of the expected dose has no meaning.

So my concern is about the percentage expected dose to that structure. That is my problem, not how many percent.

MEMBER SULEIMAN: Dr. Malmud, this is Orhan Suleiman.

CHAIR MALMUD: Dr. Suleiman?

MEMBER SULEIMAN: I tend to agree with Dr. Nag. I think part B really is more state of the practice of medicine and the intra-organ variability.

I think they change treatment fields.

I would really defer to the therapy physicists and the other radiation oncologists to confirm me on that, but I think that is a level of micro regulation.

I think A is sufficient.

CHAIR MALMUD: Thank you, Dr. Suleiman.

VICE CHAIR THOMADSEN: This is Thomadsen. May I respond?

CHAIR MALMUD: Yes. I was just about to ask for the opinion of the other three members of the Subcommittee. Thank you, Dr. --

VICE CHAIR THOMADSEN: Yes. I disagree with Dr. Orhan that this is micromanagement. It is not at all. It is dealing, as Dr. Ennis said, with a sense to structure that may be important.

As far as the levels, it was set at 150 percent of the plan to give quite a bit of room for variability in the implant. It could be 200. I think above 200, you are getting to be quite egregious. That is, even if you start out with a very low dose to start with, implant probably should be better than that.

I think that adding criteria based on a structure's tolerance would be very hard to actually

in practice regulate because there is an incredible amount of disagreement as to what a structure's tolerance would be. And, as was pointed out, that depends on the time course of the treatment. And there is limited data on what exactly the structure's tolerances are, which is one reason we did not go there. It was considered in our deliberations.

We could modify this talking -- rather than an absolute volume and dealing with a relative volume, that would necessitate that for any permanent implant, any internal structure would be completely contoured.

And that might not be feasible in structures such as the head and neck, where the structure itself may go quite a ways outside of the treatment volume or the inferior vena cava in the liver. If you're looking at a relative fraction of that organ, you probably are not going to be contouring the entire organ, in which case getting a proportion of the structure becomes very difficult in practice.

DR. NAG: This is Dr. Nag. If there is so much objection to what I said, I will withdraw my statement and leave the sentence as it is because that sentence would, therefore, by default have no meaning.

Therefore, I would have achieved my purpose. So I hereby withdraw my objection to the paragraph and would leave the paragraph as it is.

CHAIR MALMUD: This is Malmud. Thank you, Dr. Nag.

Now, we have not yet heard from Dr. Langhorst or Dr. Suh or Dr. Welsh regarding this most recent interchange. May we hear from the other members of the Subcommittee?

MEMBER WELSH: This is Dr. Welsh. As the Chair, I'll allow other members of the Subcommittee to place their opinion before --

CHAIR MALMUD: Thank you, Dr. Welsh. Dr. Langhorst? Dr. Suh?

MEMBER SUH: So this is John Suh. You know, I'm looking at the sentence again, "For all intra-target structures, such as urethra and prostate implant, the example is dose of at least 5 cc contiguously exceeds 150 percent of that structure's expected dose based on the approved pre-implant dose distribution." And so, you know, since this is an "or" statement, I am comfortable keeping that sentence in place.

I think it is important that for a normal structure -- and the urethra is a normal structure

within the prostate gland -- that there is some criteria that is set because one could conceive that someone could put a very hot seed into the next urethra inadvertently, which would give a dose much higher than the 150 percent, which would constitute a medical event because when I look at the proposed definitions, I don't see anything in here that would say that putting a much higher source strength within the urethra would be considered a medical event.

CHAIR MALMUD: Dr. Suh, so you are in favor of leaving the document as it stands?

MEMBER SUH: Yes.

CHAIR MALMUD: Thank you.

Dr. Langhorst?

MEMBER LANGHORST: Yes. This is Sue Langhorst. I know as I have gone through this process -- and I am definitely not as -- don't have the expertise that my colleagues on the Subcommittee have in regard to this. I always ask the question, is this too much regulation? Is it possible to expect upon this type of criteria?

And I know I always have some difficulty in knowing for sure whether this would be something that an inspector could come in and readily evaluate whether its criteria met or not met.

So I will defer to my colleagues as far as whether this is an appropriate item to leave in or not.

CHAIR MALMUD: Thank you, Dr. Langhorst.

And now Dr. Welsh?

MEMBER WELSH: Yes. Jim Welsh here. So I would first address Dr. Langhorst that I believe, as written, these relatively simple and, as we have heard from our conversation, perhaps overly simplified suggested parameters are going to be relatively easy to inspect and regulate upon.

I do think that Dr. Nag's point is very well-taken that for the prostate as an intra-target using the prostate for the intra-target structure -- the one that we're talking about is the urethra -- and, as currently written, would essentially never have a medical event. And I think that's worth keeping in mind. It's a subtle point, but, as we know, the urethra volume is going to be significantly less than five cc in almost all cases except it's the size of a softball.

So it's almost a moot point when it comes to the prostate, which means that maybe we do have to modify it slightly.

But I do agree with Dr. Ennis that it is

important to if we're going to have overdose as a criteria -- and I personally think that if we're going to use dose at all, it should not be for the target, but it should be for overdosing of normal structures. And in my opinion, that is what it is all about.

If you are overdosing normal structures, whether they are internal or adjacent, that is where you could get into trouble. And that is where it would be appropriate to have a medical event definition.

So I do agree with Dr. Ennis that maintaining some semblance of 2.B is worthwhile because to exclude intra-target structures is not in my opinion the ideal solution.

But then the question becomes, how does one do it? Dr. Ennis has suggested maybe 5 percent getting more than 200 percent of the dose. Dr. Nag has introduced the idea of tolerance.

Tolerance in an ideal world would be perfect. If we could just say that X cubic centimeters exceeds the tolerance and it is going to likely cause trouble for the patient, well, that would be a perfect definition. But, unfortunately, we don't work in a perfect world. And such a definition would be very difficult to implement. And, therefore, I'm not convinced that we could use the tolerance concept, as

attractive as it may be.

But we do need to have some semblance of a dose-volume relationship. That is important. If we just say 200 percent of the prescribed dose to the CTV or 200 percent or 150 percent of that structure's expected dose, then we can talk about points, point doses, which might exceed that and be absolutely meaningless clinically. So it is critical to have some sort of a volume assigned to it.

The volume for the prostate, you know, five cc, is perhaps inappropriate because it would essentially exclude the prostate from ever having a urethral overdose. On the other hand, five cc might be small if you're talking about a large liver implant. And Dr. Nag has pointed out it could be possible to overdose the IVC according to this definition.

I do think that it is important to maintain some form of 2.B in our definitions. It may need to be tweaked so that it's not a rigid five cc, which is too much for the prostate, maybe too little for the IVC or other structures.

Is 150 the correct answer, 150 of that structure's expected dose? Could we use 150 of the tolerance dose or the tolerance dose? I don't know

right now. I'm skeptical that inserting tolerance is going to be something that's inspectable.

But I do think that, as written now, it is fairly good. And I wouldn't try to change too much right here today.

CHAIR MALMUD: Thank you, Dr. Welsh. What you have done is to review the pros and cons of the current recommendations and to reaffirm your support of the current recommendations. Did I summarize what you said well?

MEMBER WELSH: Well, much more succinctly, yes.

CHAIR MALMUD: That being the case, it appears that we have a recommendation from the Subcommittee, with three of the four members, yourself included, supporting it and one abstention.

MEMBER WELSH: Right. So that Dr. Thomadsen could revisit his abstention because this is a --

VICE CHAIR THOMADSEN: I did not abstain on this, on the issue of A.2(b). My abstention was on the part B, adding to the attestations. On this issue, I am for keeping A.2(b) as it is. I am not abstaining on that.

CHAIR MALMUD: Thank you, Dr. Thomadsen, for that clarification.

Do we have a motion from the Subcommittee?

MEMBER GUIBERTEAU: Dr. Malmud?

CHAIR MALMUD: Who is that, please?

MEMBER GUIBERTEAU: This is Mickey Guiberteau. I just have a question, not being a radiation oncologist, with the language as written here. Could I ask a question of the Subcommittee?

CHAIR MALMUD: Please do, Dr. Guiberteau.

MEMBER GUIBERTEAU: I am a little confused when I read this with the word "contiguously" in parentheses. As an adverb, I would presume this is meant to modify "exceeds," which doesn't make much sense to me. If it is meant to apply to the volume, the five centimeters, does "contiguous" mean that it is contiguous or next to the structure that we are talking about, A and B, or does it mean that the five centimeters needs to be one volume and not contiguous volumes and not discrete volumes adding up to five centimeters?

MEMBER WELSH: Dr. Malmud, this is Jim Welsh. I could answer Dr. Guiberteau's question.

CHAIR MALMUD: Thank you, Dr. Welsh.

MEMBER WELSH: Dr. Guiberteau, it is intended to be continuous structure. It is contiguous anatomical structure that is one continuous piece of

tissue, rather than having a piece of tissue here, spaced by some more dose, another piece of tissue here that is a higher dose, and then a few centimeters down the road have another point that has exceeded this. It must all be in one spot because chronologically that is what makes the difference.

MEMBER GUIBERTEAU: Then I suggest we modify this to where it says, "at least contiguous five centimeters," rather than "contiguously," because that could mean that you mean contiguous to, say, the urethra, rather than the volume itself.

So I would -- you know, reading a regulation, I mean, I think it should be clearer than this. So I think it is a semantic thing, but I think it could be variously interpreted. So, you know, I would just suggest that when this is written, that we not use the word "contiguously" but -- so that it doesn't refer to exceeds but refers to the five centimeters that --

MEMBER WELSH: So if I could ask, this would be at least five contiguous centimeters?

MEMBER GUIBERTEAU: Well, that would make more sense to me because I didn't know whether it meant that the five centimeters need to be contiguous volume adding up to that or whether it's contiguous to

the structure itself, such as the urethra. So what you have said makes more sense to me and makes it clearer.

MEMBER WELSH: Okay.

VICE CHAIR THOMADSEN: This is Thomadsen. I would support that change. I think it would be a good change in both A and B.

CHAIR MALMUD: Thank you.

Dr. Langhorst? Dr. Suh, do you agree changing the "contiguously" adverb to an adjective, "contiguous," preceding the "centimeters"?

MEMBER SUH: This is John Suh. I agree with the suggested change.

MEMBER LANGHORST: This is Sue Langhorst. I agree, too.

CHAIR MALMUD: So the recommendation is changed, dropping the "(contiguously)" and, instead, using it as an adjective with the word "contiguous," preceding the "centimeters" in both subheadings 2(a) and 2(b).

Is there any objection to that from anyone?

(No response.)

CHAIR MALMUD: Hearing none, we will accept that as a change in the recommendations.

Is there any further discussion of this

recommendation?

VICE CHAIR THOMADSEN: Yes. This is Thomadsen. And I was the author of the minority report. And I should explain my issues to the Committee, if I may.

CHAIR MALMUD: Please do.

VICE CHAIR THOMADSEN: There were several changes compared to the previous report. The first one that I find a bit of a problem is the change to the treatment site, as opposed to the use, the explicit use, of the planning target volume or the clinical target volume. And that would be the treatment site as used in this report would mean where the sources are to be placed. And that would be exclusively the planning target volume; whereas, in the prescription, the clinician, the authorized user, is going to be defining the dose to be delivered to the clinical target volume.

And so we have a situation where the term "target site" would now be differently used in the written directive and in the prescription. And I think that this is potentially leading to confusion and misunderstanding.

The second issue is the dropping of the octant criteria. And this was to catch those implants

that would have all the sources bunched not where they were supposed to be, but all in one location, which would not be crossed with the 20 percent criterion.

The octant, unlike it is being characterized in discussions here, is not that complicated of an issue since it is just riding the target in half along each of the axes. And it could be along any axes that would give you the distribution that would pass or, as I point out in the report, you could even just say that if you divide along any axis the targets in half, 20 percent of the sources should be in either side of that dividing.

So it really is not difficult. And, as far as causing discussions between regulators and users, if you can find axes that work, then it is fine. You don't have to argue anymore.

Would it be extra work for people? Absolutely not because most of the time as long as in the previous report, the D-90 was greater than 60 percent, you wouldn't ever have to do the calculation of these distributions, which that brought us back to the discussion of the dropping of the D-90.

In the previous report, the use of the D-90 as being less than 60 percent was exclusionary criterion. If the implant had 20 percent or more of

the sources outside of the PTV, it could still be a good implant and deliver perfectly fine therapy. We have seen examples of that.

If the seeds were bunched, they're bunched in a way that still treated the target. That also should be excluded as a medical event. And the D-90 was the exclusionary criterion, saying that if there was going to be no harm to the patient due to either of these failures to just what you had planned, then it's not a medical event because the patient was treated just fine. And, as always, with any of these, if you plan a de-escalation of dose or an escalation of dose in one place or another or it's during the implants, you find anatomically that you cannot do the implant that you had planned, those, of course, trump any of these situations.

And, finally, the issue that I objected to probably the most was the attestation. And, as I point out, I do not think it is a good regulation at all, nor good medicine approach.

If putting the practitioner in the position of attesting to that what they did is what they were supposed to have done, if things don't go exactly how they wanted to do, they may be persuaded to attest that, well, that is what they wanted to do,

it's perfectly fine.

Also, you are putting the authorized users in a position where the regulators and the users may disagree with how close to the intended implants the practitioner actually executed.

The discussion of this could go on in many different implants where the attestation would be questioned. If the attestation isn't being questioned at all, it certainly could be used to assess that the sources went where they should have gone, regardless of there being more than 20 percent outside of the target. You can do away with both criteria for the implant and just have the attestation left over. And this is a very strange process on the regulatory side.

By having any criteria, are we impinging on the practice of medicine? Well, this has come up many times at the ACMUI when we talk about possible medical events. And for the protection of the public, including the patients, it has always been decided that there is a responsibility on the part of the NRC to hold the practitioners responsible for what they do. And this should be something that could be quantitative, as opposed to just taking the practitioners' word that they did exactly what they felt they should have done.

Without addressing the four items that I list in the minority report, I think the medical events criteria that we have come up with fails to be robust, as far as dealing with a quantitative and practically applicable definition for medical event. I think it would cause more confusion and more distention between regulators and authorized users. I think it will potentially result in the reporting of medical events that should not be seen as medical events.

CHAIR MALMUD: Thank you, Dr. Thomadsen.

Well, the items are in the minority report, which are found on pages 8 through 12 of the report. There are differences in your minority report from that given to us by the majority of the Committee. What are you recommending instead or are you not recommending?

VICE CHAIR THOMADSEN: I would recommend going back to the recommendations in the previous report, the 2011 November report. I think that they were well-thought-out and addressed the concerns that have been expressed in the meeting. They do not follow the recommendations of many of the people who are in the meetings, but they don't really run contrary to the goals of what has been expressed. I think that it

would clarify the situation much better than the current proposed draft.

CHAIR MALMUD: Thank you, Dr. Thomadsen.

Dr. Welsh, do you wish to respond?

MEMBER WELSH: I do. Thank you.

So I will reply first that I think that the October 2011 version that Dr. Thomadsen is in favor of is actually a very good definition. It was well-thought-out. And it has certainly got a lot of merit.

But it is worth remembering that a large professional organization, namely ASTRO, of which we have representation on the phone today, actually wrote a letter to NRC and ACMUI expressing opposition. So this I think indicates that if the largest body of radiation oncologists is expressing concern with the definition, it certainly merits further consideration.

After that consideration, I, personally, as a member of this Subcommittee, not speaking for everybody -- I can reply to Dr. Thomadsen's concerns point by point. Number one, the term "treatment site," we have argued at ACMUI meetings since -- well, I don't even remember when. It goes probably back to 2005 or so.

VICE CHAIR THOMADSEN: Two thousand six.

MEMBER WELSH: Okay.

-- that we should perhaps be using terminology like "CTV," "PTV," "gross tumor volume," et cetera. But at that time, the terminology was relatively new to NRC and new to some practitioners as well. But now, fast forwarding to 2012, this is not terminology that is new or unfamiliar to anybody.

And, therefore, if we are too restrictive in any form or fashion with our definitions about volumes, we are potentially causing some conflict.

And, therefore, I personally favored use of the term "treatment site," which gave a little bit more latitude to the authorized user to be talking about a GTV in this case or CTV or prescribing to a PTV depending on the individual authorized users and the institution's preference.

Some institutions always prescribe to a GTV. Others prescribe to a CTV. Others include the expansion and prescribe to a PTV. "Treatment site" is a generic term that would encompass all of them. So that's why I remained in favor of "treatment site."

As to the octet concept, yes, it is relatively simple, any three orthogonal axes. But I anticipate that, in actual practice, the three orthogonal axes could be challenging. What if somebody

says, "Here is the middle. We're going to put a line down"? Well, no, no. Here's the middle. It's two millimeters to the left. No. Here's the middle. It's a millimeter to the right of what you are saying the middle is. You get one of those axes off. The whole concept of the octants becomes challenging.

What about that situation where you come up with, say, orthogonal axes that are perfectly set up but then it's not a medical event but then if you rotate it five degrees, you find that the seeds are not perfectly distributed. Well, in principle, it might be possible to have a medical event triggered in one set of orthogonal axes and not another.

And I know Dr. Thomadsen has thought about this and has a response. But to me, it would seem like it is going to be a challenge from the regulatory perspective.

Then, going on to the D-90 greater than 60 percent, I think it is worth emphasizing what Dr. Thomadsen has said over and over again, that this is not to trigger a medical event but to prevent a medical event. In essence, D-90 greater than 60 percent means you don't have to even look at the octants, everything is okay.

So superficially I would say, man, that is

great. That is just what we want. But then I start thinking that they're using the D-90, the D-90, which we have opposed so, so vigorously for the past six years, that, even though it's being resurrected here not to trigger an event but to prevent the event, conceptually I remain opposed to it. That doesn't mean that I can't be swayed by logical argument, but use of D-90 just is anathema to the ACMUI conceptually over the past six years.

But I think that Dr. Thomadsen's point that the D-90 is being used here not to trigger but to prevent a medical event is worth emphasizing because that is an important point.

Finally, the argument that Dr. Thomadsen uses opposing the attestation, I would submit that it is not entirely subjective, but there is an objective component to it. And we discussed that at the beginning of this teleconference.

By putting the word "final" there, the "final" plan, we have something that is objective, is on the computer, and can be compared to the seed distribution so that if somebody puts all of the seeds in one bunch and then you look at the seed distribution on the computer according to plan and go all around the perimeter, you know that there is

something wrong. The authorized user cannot attest that the seeds are in the right place. And if they do, they are going to be caught because this is fraud and they would be exposed. But now they must attest or sign something that says that they put the seeds in accordance with the plan or, else, if they don't sign it, well, then it's going to be a red flag that will trigger an investigation.

So those are the main points that I have in response to Dr. Thomadsen.

CHAIR MALMUD: Thank you, Dr. Welsh. I assume you are speaking on behalf of yourself, Dr. Langhorst, and Dr. Suh as the three members of the Committee who supported this recommendation.

MEMBER WELSH: I believe that I am, but I think that given that ASTRO was an organization that opposed our 2011 version -- and if there are ASTRO representatives on the line, they should perhaps speak up now, too. But I believe and I hope that I am speaking for the rest of the Subcommittee.

DR. ENNIS: This is Ron Ennis. I would be happy to address Dr. Welsh's comments. I am on the call representing ASTRO. I think he summarized ASTRO's position and most of the issues well, but I will elaborate a little bit.

Using a D-anything, D-x, while used as a tool for clinicians to assess their implant, it is fundamentally flawed and really can never really be fully overcome. And, therefore, we have been unhappy with it as a regulatory criterion because of the implications thereof.

The fundamental flaws are two. A) it is largely affected or tremendously affected by the amount of prostate swelling or edema that will occur after the procedure, which is out of any clinician's control. And that can easily create a quality implant or a quality execution, at least, into a medical event if we use a D-90 criteria.

And b) it is highly dependent on prostate imaging quality. And there is a lot of variation in the different imaging modalities and their ability to define the borders of the prostate, which, of course, is the volume on which the D is calculated. And, therefore, if you use one imaging modality, you can easily get a very different D-x than you will with another imaging modality, MR, CT, and ultrasound being the three main modalities.

So it is such a fundamentally flawed measurement. While a good tool for the clinician to use, it doesn't seem to be logical as a regulatory

criterion. Twenty percent of seeds outside of the area that is to be implanted, what's called treatment site in the current document, is something that is not affected by any of these fundamental flaws. It is objective. And we, therefore, think that that is really the best way to define a medical event.

In terms of the other specific things that were brought up, we agree with Dr. Thomadsen that treatment site is a little vague and could potentially allow practitioner to say, "Well, that was my treatment site."

And PTV would seem to be a good definition in that that is the largest of the volumes that we are trying to treat. And generally you would want, you know, certainly all of your seeds to be within that structure.

An alternative could be to say treatment site as defined by the practitioner on the plan or something along those lines to allow them to say PTV or PTV plus another centimeter or something along those lines. But just saying treatment site to us, we agree with Dr. Thomadsen. That's a little vague.

Just backing up to octant concept, I think it has already been well-spoken, its limitations. Just another to me likely-scenario with a lot of

implants would be, as one was dividing the prostate along these different axes, seeds would cross those axes or be aligned along those axes. There are many seeds within the prostate, and it's highly likely that many would be -- and then which octant do they get counted in? And they got double counted in each of the two octants on which they border. And, again, this could be just, you know, a quagmire that wouldn't get anyone anywhere.

I do think the attestation at the end of the procedure is key to allow the flexibility but also allow the regulator to come in and say, "Well, you know, this is nothing like your plan" and allow the practitioner to be held to a standard saying, "You said you implanted as your plan" or you were specific in what you did differently and why. We do think that it ought to say, you know, a justification for why.

And, to get to Dr. Thomadsen's point about the regulator and practitioner fighting, I think a provision that the case be reviewed by an independent radiation oncologist could be put in as a message for evaluating.

And that independent reviewer would assess the written directive, final written directive, to say, "Okay. What was the reason in the attestation for

why the plan was changed? Is that reasonable? Is that what happens? And was this modification done in a reasonable fashion?"

CHAIR MALMUD: Thank you, Dr. Ennis, for your explanation of ASTRO's opinion.

VICE CHAIR THOMADSEN: This is Thomadsen. May I make a comment?

CHAIR MALMUD: Yes, Dr. Thomadsen?

VICE CHAIR THOMADSEN: Discussing some of the points made, particularly with regard to the use of D-90 and its sensitivity to imaging, many of the same arguments would apply to evaluation of whether 20 percent of the sources or more lie outside of the treatment volume if the imaging is that dependent. So that argument itself does not go against D-90 for 20 percent of the seeds.

The fact that the D-90 may be sensitive to all of these things -- and it is. As I point out in my minority report, all of the reasons that we objected to the use of D-90 for defining an event still hold. And they are all valid.

The use of D-90 as an exclusionary tool, on the other hand, simply means that if you had edema and the D-90 were somewhat low and you had -- and implants were 20 percent or more of the sources were

outside of the treatment site, if the D-90 were fine, then you would not have a medical event. And you wouldn't think about this case further.

If, for any of those reasons, the D-90 was less than 60 percent, then you still would have the medical event, just like you would if you had no D-90 criterion, because the 20 percent of the sources were outside of the treatment site.

So, even though the D-90 might be affected by all of the things that we say that it is, it could prevent the unnecessary reporting as medical events perfectly fine implants, where 20 percent of the seeds might be out of the treatment volume. And it might not work if you exclude others. But in its absence, none of those, none of those would be excluded.

So far the argument on the octant and trying to find axes that will or will not pass, do remember that in a normal distribution, you would have 12 and a half percent of the sources in each octant.

The criteria was having five percent in each octant. If you're just making small changes in the axes, you aren't going to have that type of sensitivity to bring a lot of discussion into this. And if we saw, as I point out in the minority report, that if you find axes that work and you don't have a

problem, that eliminates the discussion between the user and the regulator, who would say, "Well, it worked in your axes but not in mine." The ties goes in favor of the authorized user.

So I don't think that those objections really hold.

DR. NAG: Hello. This is Dr. Nag. Can I add a couple of comments?

CHAIR MALMUD: You may, but I want to make certain that Dr. Thomadsen had completed his --

DR. NAG: Oh. I thought he had finished.

VICE CHAIR THOMADSEN: Yes, I had.

CHAIR MALMUD: Thank you.

Dr. Nag?

VICE CHAIR THOMADSEN: All yours.

DR. NAG: Okay. So this is Dr. Nag. A couple of comments on some of these points. First of all, let's start with the octant concept.

The octant concept is a beautiful function, works very well on a theoretical basis from a physics standpoint. However, the problems in that particular thing is that, number one, when we are doing our implants, we are not putting offsets when I am putting my thing.

Number two, more important than that,

let's say all of the things were put in one place. If octant concept works, if you are trying to homogeneously implant a certain organ, at this time clinically we do not want to implant homogeneously. We want to implant more in one area, less in another area because certain areas have either normal tissue that we want to avoid or certain areas have high risk of tumor that we want to get higher results.

And, therefore, doing an offset will not work because just an octant will have higher dose. And just an octant will have a much lower number of seeds because that is our intention. And it may be even lower than the five percent that was trying to obtain.

It also cannot work, even if you have bunched all the seeds. You wanted to try and get the unusual situation where all the seeds may be bunched into one area. I can bunch all the seeds in the middle of the prostate. And you have a reaction. And I'll have 12 and a half percent in each of the octants. And I am going to the urethras. So even of the octant concept is not the same.

So, because of all of these reasons, I would not want the octant concept in a regulatory sense. You can use it in research to do some research

parameters and diagnosis and so forth but not for regulation.

Secondly, let's talk about the treatment site. I think I agree with Dr. Thomadsen that there is some ambiguity about treatment site. We had mentioned about this in the ASTRO report that came out in Practical Radiation Oncology dealing with medical event destination from permanent brachytherapy in November or October through December 2001, Practical Radiation Oncology I think still deserves another reading.

The site that we are talking about is somewhat ambiguous. When we are talking about the prescription, we are talking about we are prescribing through the CTV. And when we are talking about analysis and how many percent is outside the treatment site, we are really talking about the PTV.

So I think I agree with Dr. Thomadsen if we revise these two that the treatment site for the prescription would be CTV, outside the treatment site 20 percent and that would be the PTV. I think that would help to clarify the method to some extent.

The third one is the octant concept. Again, I agree with Dr. Ennis that the octant concept has to be removed from the plan for many reasons,

including the plan that authorized user has no control of the distribution of the seeds after it has been released. And we talked about the edema and so on and so forth. Those are outside the control of the authorized user.

Well, these are just some of my comments. Thank you.

CHAIR MALMUD: Thank you, Dr. Nag.

Are there comments from other members of the Subcommittee or from other members of the ACMUI?

VICE CHAIR THOMADSEN: This is Thomadsen. May I reply to a couple of his comments?

CHAIR MALMUD: Please do.

VICE CHAIR THOMADSEN: The first issue is looking at the octant and whether it only works for homogenous distribution and there are problems otherwise.

In the proposal, it was assumed that many of the times, the authorized user would want to have differential distribution of the sources. That worked into the written directive. That would not then cause a -- that would not trigger an event based on the octant, that the authorized user said that they aren't going to be using a homogeneous distribution.

The question that they don't rely on the

distribution to get the sources in the octant, that's perfectly fine. They don't have to find it to have it evaluated that way. Most implants do work out with the distribution working pretty much into the octant, even with some escalation and de-escalation. So the fact that the authorized user has control over the evaluation of this eliminates that as a problem.

The question of whether or not all of the seeds clustered around the axis would be caught, it may not be caught. Particularly it wouldn't be of interest if the D-90 still was 60 percent according to the previous version of this report.

Also, if that happened, how many cases could that possibly be where the sources would all be congregated around the ASTRO? And if we don't catch that one, fine. It got to be a very few, if any, cases that could ever happen. Once again, the discussion turns to D-90 and its problems, as I said last time, the D-90 as a trigger for a medical event has been completely argued. And we all know that that is not a good tool, but that is an exclusionary device.

None of the arguments about it hold. It's still a good exclusionary device if it eliminates a good proportion of unnecessary medical events.

I'm done.

CHAIR MALMUD: Thank you, Dr. Thomadsen.

MEMBER WELSH: This is Dr. Welsh. If there are no immediate replies to Dr. Thomadsen?

CHAIR MALMUD: Please, Dr. Welsh.

MEMBER WELSH: I would start off by saying I agree with Dr. Thomadsen that D-90, as bad as it is for the target, if it was going to be used at all in regulation, it would be reasonable to resurrect it as an exclusionary criterion, rather than a defining perspective, defining parameter, for medical event.

I still stand by my initial statement that I am opposed to D-90 in all forms and fashions. It is very arbitrary. That's where I am today.

Regarding the point about the treatment site, we have heard Dr. Thomadsen's perspective as well as Dr. Nag and Dr. Ennis representing ASTRO. My reply is that the reason why I favor treatment site in general, the defined term "treatment site," is because I was fearful that NRC now that they understand CTV, GTV, PTV might arbitrarily pick one of those three for us and not give us the latitude to say in this case I am talking about the PTV or I am accustomed to using the GTV for this list. And now NRC is intruding into the process of medicine by picking one of those three volumes and saying, "You must use CTV here."

And that is why I thought treatment site, being generic and giving us latitude to decide which one of those is being alluded to here, was preferable than allowing NRC to tell us "You must be talking about the CTV in your written directive," no ifs, ands, or buts. And that is the reason why I favored the treatment site.

If NRC rulemaking is going to allow us to make the decision, are we talking about GTV here, PTV, CTV? That would be fine, but I was fearful that NRC rulemaking might pick one of those and say, "Here is how it is. Here is how you have to comply from now on." And that is something I didn't want to run the risk of.

As far as Dr. Thomadsen's point about the octants, possibly there being a discrepancy between an unusual case where if the authorized user says, "Well, look at these octants. All is fine" but now the inspector said, "Well, I rotated at three degrees. And look at these octants. All is not fine," the tie goes to the authorized user.

I'm not so convinced that NRC would say that the tie goes to the authorized user. They might say that the tie goes to the inspector.

If we can find any example where the

octant concept is violated, that's a medical event. And, therefore, rather than decreasing the number of medical events, it might, surprisingly, increase them.

Finally, regarding the effect of edema on D-90, yes, we know that edema causes changes in D-90 that would be unfavorable for the authorized users with the current definition.

But I'm not so sure that volume changes due to edema affect the 20 percent outside the treatment site concept as much as they affect D-90.

So yes, there would be subtle impact on the 20 percent, but major impact on the D-90. And, therefore, I don't know that that argument really holds about the edema.

Those are my comments.

CHAIR MALMUD: Thank you, Dr. Welsh.

I think we have heard the arguments expressed eloquently of the majority of the Subcommittee as well as the minority Subcommittee. Do we have any additional comments from members of the public?

MR. LIETO: Yes.

CHAIR MALMUD: May I ask who is speaking?

MR. LIETO: This is Ralph Lieto.

CHAIR MALMUD: Yes, Ralph?

MR. LIETO: I have a couple of comments. I would agree with the comments regarding the proposed definition A.1 regarding treatment site. This has been argued in previous ACMUIs. And the overwhelming agreement by the various ACMUIs as well as the general public was that plan target volume was the way to go, instead of the treatment site.

My second comment has to do with A.2 regarding the dose-based criteria that are being proposed by the Advisory Subcommittee. In listening to the discussions by the various members from ASTRO and the practitioners and Dr. Thomadsen, there is obviously a great inconsistency and disagreement on some of these aspects.

I would like to point out that during the workshops when this proposed rule was being addressed, which did not include a dose-based criteria, that overwhelmingly the various professional societies and workshop attendees agree that an activity-based or source strength criterion was the way to go and that it should not involve a dose-based criterion.

And there seems to be -- with these changes that are being added to A.2, this just seems to have taken what was thought to be a healing sore and picked the scab and raised it into an open wound

again.

And my recommendation is that the dose-based criteria be eliminated altogether. There are inconsistencies and agreement and also would be consistent with what the workshops and various public input during the previous ACMUI meetings on this subject have supposed, which is a source strength-based criterion.

And one other -- and I have a question to the ACMUI Advisory Committee -- was this dose-based criteria, this would be assessed when: at 1 day or 30 days when they do the post-implant assessment? Was that the implied intent here?

CHAIR MALMUD: Thank you, Mr. Lieto. I will direct your question to Chairman Welsh of the Subcommittee.

MEMBER WELSH: So first my reply to Mr. Lieto is that yes, we have, the ACMUI and the Subcommittee, in particular, have, argued against use of dose for many years, but we have been focusing primarily on dose when it comes to targets because the current definition leads to ambiguity. The one that is in practice right now and is triggering 100 medical events per year is ambiguous enough and problematic enough that we have argued for the dose to the target

for this time.

So in the process of trying to revise the medical event definition, we went back to some very basic concepts. And the basic concept that I'm alluding to here is the overdosing of normal tissue, which can leave harm to the patient. And if we focus on that concept, it does seem to make sense that dose could be used appropriately and understandably used for overdosing of normal tissue.

So when we are talking about dose at this point here, I am opposed to using dose at all under any circumstance, D-90 even for the target, even if it's exclusionary.

So no dose to the target is my perception. Dr. Thomadsen has pointed out possible use of dose as an exclusionary measure. But I don't think we are opposed to the modern concept of using limited use of dose when it comes to normal tissue overdose because that is what we do in actual practice of medicine. If we're overdosing the structure, that is a medical problem. And it's also a radiological problem. And it's reasonable to have it incorporated into the NRC's medical event definition.

As far as when to evaluate this, I think that it is important to have some kind of limitation.

You don't want to evaluate this years later. But you don't want to do it too soon for the reasons that have been alluded to many times about the problems with edema that give you a false picture, quite literally.

And so it might depend slightly on the particular isotope and the half-life chosen, but generally there are criteria or guidelines that are used for when is best to do a post-implant dosimetry. And the post-implant dosimetry that is used for judging the quality of the implant from the practitioner's perspective and being able to tell the patient what the outcome is likely to be in terms of cure and complications is also the same post-implant dosimetry study that would be used for defining whether or not there is an overdose to the normal structures.

And it might be approximately six to eight weeks after the implant, but it might vary.

CHAIR MALMUD: Thank you, Dr. Welsh. So you are replying to Mr. Lieto's question by indicating that there is no specific time for recommendation, but that you would entrust that to the medical practice, rather than the NRC?

MEMBER WELSH: I would because, as I mentioned earlier, if you have a cesium-131 implant

with a half-life of approximately 10 days, you might choose to do your post-implant dosimetry at a very different time point from I-125 implant with a half-life. So there should be some latitude there.

And it would be inappropriate for a regulatory body to say, "It must be done at this time interval." I think that is something that should be up to the individual treatment team depending on the specific isotope.

CHAIR MALMUD: Thank you, Dr. Welsh.

I think that we have had a two-hour lively discussion regarding the recommendations, the minority opinion, with the input of ASTRO and interested members of the public. If we may, we can move this recommendation to the full ACMUI, which is in attendance on this Committee. Is there such a recommendation of the Subcommittee be brought forth to the ACMUI?

MEMBER ZANZONICO: This is Pat Zanzonico. I would make that motion.

CHAIR MALMUD: Is there a second to the motion?

MEMBER WELSH: I second it.

CHAIR MALMUD: Dr. Welsh seconds the motion. Can we move the motion forward, having heard

the discussion?

(No response.)

CHAIR MALMUD: I hear no objection to moving the motion forward. We'll move the motion forward. All of the members of the ACMUI in favor please indicate aye.

(Whereupon, there was a chorus of "Ayes.")

CHAIR MALMUD: Are there any nays?

VICE CHAIR THOMADSEN: Yes, nay.

CHAIR MALMUD: May I ask who says, "Nay"?

VICE CHAIR THOMADSEN: Thomadsen.

CHAIR MALMUD: Dr. Thomadsen? Thank you.

Are there any abstentions?

(No response.)

CHAIR MALMUD: Hearing none, the motion moves forward with one negative, the rest positive votes.

Is it necessary -- I am asking now this of NRC staff. Is it necessary for us to indicate the names of each of those who have voted because we are now almost two hours into the Committee meeting. It's certain that we have a majority.

MR. FULLER: To answer your first question, no. I don't think we need -- well, we have called the roll. We have one abstention. We know who that is. So

by process of elimination, we know who voted.

CHAIR MALMUD: Well --

MR. FULLER: But one question I have for clarification now, when you say "move it forward," it's with the one change that was adopted early in the meeting, correct?

CHAIR MALMUD: That is correct. It was the insertion of one word.

MR. FULLER: Okay.

VICE CHAIR THOMADSEN: One question, was there not also the change of "contiguous"?

MS. COCKERHAM: This is Ashley. I have that change noted as well.

VICE CHAIR THOMADSEN: Yes. Thank you.

MEMBER WELSH: And this is Jim Welsh. If I could raise one last time that question about treatment site versus a specific GTV, CTV, or PTV. I think you have heard my argument that using the generic term "treatment site," which is defined in the terminology section, our glossary, allows us to select which one of those three volumes we want to use and the reason. My preference was that I don't want NRC rulemakers to say, "You must use CTV, end of story."

And, having stated my argument, I am wondering if those who opposed the use of "treatment

site" still remain opposed or if their opinion has changed?

CHAIR MALMUD: If I may, Dr. Welsh, the recommendation includes the terminology "treatment site" and, therefore, was just approved by the ACMUI.

MEMBER WELSH: I think there was opposition from the public and from some members which I think -- I remain in favor of using the generic term --

CHAIR MALMUD: When you say, "I," you mean the majority of the Subcommittee, which made the recommendation to the ACMUI, do you not?

MEMBER WELSH: Yes. Yes.

CHAIR MALMUD: Thank you. I just wanted to clarify that for the record, that three of the four members of the Subcommittee brought forth this recommendation, which we correctly now identified with two changes. One was the change of the adverb to the adjective. The other was the addition of one word.

I wanted to thank all of the members of the Committee; the diligence of the Subcommittee, including the thoughtfulness provided by the member of the Subcommittee which provided the minority report; the participation of members of the public, including ASTRO and all of those who spent the two hours with us in resolving this very difficult and challenging

problem.

If I may in closing make a final comment, having passed the motion. That is, I think we must be very careful in the future of not attempting to make regulations that apply --

THE REPORTER: Mr. Chairman, I am going to have to interrupt. This is the Court Reporter. I am hearing phone interference.

CHAIR MALMUD:I am hearing the interference as well.

THE REPORTER: Yes. Participants, if you are not speaking, please mute your telephones. If you don't have a MUTE button, *6 works.

CHAIR MALMUD: Thank you.

THE REPORTER: Thank you, sir.

CHAIR MALMUD: Having passed the resolution, the recommendation, what I am now saying as a final comment is it is very difficult for us to make a resolution or recommendation which is applicable across an entire specialty field by trying to apply it broadly to many different organs, for example, in this case and make it at the same time a rule which is applicable and enforceable. And we may in the future need to look at individual organs should the need arise without prejudice in an effort to make

the rules easier to apply and easier to understand than those which would be applicable across all organ systems within the body, regardless of their location.

One of the discussants pointed out very eloquently that the issue of dealing with the prostate is very different than dealing with sites that might be in the head or neck. And, therefore, applying the same rules to each different part of the anatomy of the human body may not be practical under certain circumstances. And in the future, we should probably consider that, should the need arise.

It's just an editorial comment which might be applicable in the future, but was not meant to alter any of the decisions or recommendations made today.

Once again I want to thank all of the members who participated in this conference call. Thank you for your time, your thoughtfulness, your effort, and your attendance.

MR. FULLER: Dr. Malmud?

CHAIR MALMUD: Yes? Who is speaking, please?

MR. FULLER: This is Mike Fuller with the NRC.

CHAIR MALMUD: Yes?

MR. FULLER: If you might, I mean, if you would, before you adjourn the meeting, Brian McDermott had to leave, but our Acting Deputy, Pam Henderson, has some remarks she would like to make before you adjourn the meeting if that would be okay.

CHAIR MALMUD: Absolutely. I was not aware that such a request existed. By all means, go ahead.

MR. FULLER: Thank you.

MS. HENDERSON: Hi. This is Pam Henderson. The NRC staff recognizes the challenge associated with reaching consensus recommendations on this important subject.

On behalf of FSME, I would like to thank the ACMUI members for all of their efforts on permanent implant brachytherapy guidance and, in particular, their openness and willingness to work with the input from stakeholder groups. This is really in line with NRC's values and our ways of doing business. Thank you.

CHAIR MALMUD: Thank you. And thank you for the comments from the NRC.

Is there a motion for adjournment?

MEMBER WELSH: So moved.

CHAIR MALMUD: Thank you. Our meeting is adjourned.

(Whereupon, the foregoing matter was concluded at 2:06 p.m.)