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NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

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MEETING

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MONDAY,

APRIL 11, 2011

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The meeting was convened in room T2-B3 of Two White Flint North, 11545 Rockville Pike, Rockville, Maryland, at 9:00 a.m., Leon S. Malmud, M.D., ACMUI Chairman, presiding.

MEMBERS PRESENT:

LEON S. MALMUD, M.D., Chairman

BRUCE THOMADSEN, Ph.D., Vice Chairman

DARRELL FISHER, Ph.D, Member

DEBBIE GILLEY, Member

MILTON GUIBERTEAU, M.D., Member

SUE LANGHORST, Ph.D., Member

STEVE MATTMULLER, Member

JOHN SUH, M.D., Member

ORHAN SULEIMAN, Ph.D., Member

WILLIAM VAN DECKER, M.D., Member

MEMBER PRESENT (cont'd):

JAMES WELSH, Ph.D, Member

PAT ZANZONICO, Ph.D., Member

MEMBERS ABSENT:

CHRISTOPHER PALESTRO, M.D., Member

NRC STAFF PRESENT:

JIM LUEHMAN, Deputy Director, Division of Materials Safety and State Agreements

MICHAEL FULLER, Alternate Designated Federal Officer

SOPHIE HOLIDAY, Alternate ACMUI Coordinator

NEELAM BHALLA

JUNE CAI

SUSAN CHIDAKEL

SUSAN E. COOPER, Ph.D.

SAID DAIBES, Ph.D.

SARENEE HAWKINS

DONNA-BETH HOWE, Ph.D.

DEBORAH JACKSON

ANDREA KOCK

VARUGHESE KURIAN

ED LOHR

JULIE MARBLE, Ph.D.

NRC STAFF PRESENT (cont'd):

KEVIN O'SULLIVAN

PATRICIA PELKE

JOSEPHINE PICCONE, Ph.D.

GRETCHEN RIVERA-CAPELLA

SUSAN SALTER

GLENDA VILLAMAR

SHIRLEY XU

MEMBERS OF THE PUBLIC PRESENT:

KEITH BROWN, University of Pennsylvania

WILLIAM DAVIDSON, University of Pennsylvania

LYNNE FAIROBENT, American Association of Physicists in Medicine

KAREN LANGLEY, University of Utah

RALPH LIETO, St. Joseph Mercy Hospital

CANDI MCDOWELL, Georgetown University

JANETTE MERILL, Society of Nuclear Medicine

HERBERT MOWER, Ph.D., American Association of Physicists in Medicine

MIKE PETERS, American College of Radiology

AMANDA POTTER, American Association of Physicists in Medicine

JOE RODGERS, Theragenics

GLORIA ROMANELLI, American College of Radiology

MEMBERS OF THE PUBLIC PRESENT (cont'd):

CONOR SCHMERTZ, George Washington University

DANNY SONG, M.D., American Society for Radiation Oncology

CINDY TOMLINSON, American Society for Radiation Oncology

ANN WARBICK-CERONE, MDS Nordion

JENNA M. WILKES, American Society of Nuclear Cardiology

GARY E. WILLIAMS, Veterans Health Administration

TABLE OF CONTENTS

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

(9:00 a.m.)

CHAIR MALMUD: Good morning, ladies and gentlemen. If you would all be seated, we would like to begin the program promptly and try to stay on schedule.

Thank you. I will begin by introducing Mr. Luehman, who will formally open the meeting.

MR. LUEHMAN: Go ahead, Mike.

MR. FULLER: Okay. As the Alternate Designated Federal Officer for this meeting, I am pleased to welcome you to this public meeting of the ACMUI. My name is Mike Fuller, and I am the team leader of the Medical Radiation Safety Team and 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.

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 April 29, 2011, edition -- I think that should be March 29th edition of the Federal Register.

The function of the Committee is to

advise the staff on issues and questions that arise on the medical use of by product 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 issues 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 members participating today. Dr. Leon S. Malmud?

CHAIR MALMUD: Here.

MR. FULLER: Dr. Bruce Thomadsen?

VICE CHAIR THOMADSEN: Here.

MR. FULLER: Dr. Darrell Fisher?

MEMBER FISHER: Here.

MR. FULLER: Ms. Debbie Gilley?

MEMBER GILLEY: Here.

MR. FULLER: Dr. Mickey Guiberteau?

MEMBER GUIBERTEAU: Here.

MR. FULLER: Dr. Sue Langhorst?

MEMBER LANGHORST: Here.

MR. FULLER: Mr. Steve Mattmuller?

MEMBER MATTMULLER: Here.

MR. FULLER: Dr. Christopher Palestro?

(No response.)

Dr. John Suh?

MEMBER SUH: Here.

MR. FULLER: Dr. Orhan Suleiman?

MEMBER SULEIMAN: Here.

MR. FULLER: Dr. William Van Decker?

MEMBER VAN DECKER: Here.

MR. FULLER: Dr. James Welsh?

MEMBER WELSH: Here.

MR. FULLER: And Dr. Pat Zanzonico?

MEMBER ZANZONICO: Yes.

MR. FULLER: Okay. I can see that a quorum has been met by the presence of at least seven members.

I now ask NRC staff members who are present to identify themselves. I will start with individuals in the room here. I would also like to add that this meeting is being webcast, so other individuals may be watching online.

Okay. Of course, my name again is Mike Fuller.

MR. LUEHMAN: Jim Luehman.

DR. HOWE: Dr. Donna-Beth Howe.

DR. DAIBES: Said Daibes.

MS. BHALLA: Neelam Bhalla.

MR. LOHR: Ed Lohr.

MR. O'SULLIVAN: Kevin O'Sullivan.

MS. RIVERA-CAPELLA: Gretchen Rivera-Capella.

MS. HOLIDAY: Sophie Holiday.

Ms. CAI: June Cai.

MR. FULLER: Okay. Do we have other members of the NRC staff?

DR. COOPER: Dr. Susan Cooper.

DR. MARBLE: Dr. Julie Marble.

MS. SALTER: Susan Salter.

MR. FULLER: Okay. Thank you.

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

Okay. At this point, I would like to turn it over to Mr. Luehman, who has some opening remarks.

MR. LUEHMAN: Good morning. I just would

like to welcome the members of the Committee. I spoke briefly in the closed session to I think most of you, but I will reiterate what I said then. Rob Lewis, who is our normal Division Director, Rob has -- is acting as the Deputy Office Director for the Office of FSME.

After Charlie Miller -- Dr. Charlie Miller announced his retirement as the Office Director, he was requested by the Executive Director for Operations to head up the NRC effort to do a review of the events in Japan. And so effective last week Dr. Miller left FSME. Scott Moore, who was acting as the Deputy Director, is now the Acting Director, and Robb is the acting Deputy Director presently.

So he is normally here, but I will be taking his place. All the "actings" will probably go on for some period of time, but appreciate all of the members being here. I appreciate that this -- I think Mike is going to get into it a little bit more, but this meeting I think is going to be a little bit different than previous meetings in that we hope to solicit the Committee's input on a range of subjects that the Commission has directed us to have some public meetings on.

And so to the extent that we can get the public -- I mean, excuse me, the Committee's insights on those to help shape the workshops that we intend to have on these issues, that would be much appreciated. And so with that, I will turn it back over to Mike.

MR. FULLER: Okay. Dr. Malmud?

CHAIR MALMUD: Thank you. The next item on the agenda is Old Business, which Sophie Holiday will introduce for us.

MS. HOLIDAY: Okay. I included these charts inside of your binders, and I color-coded them so you can know what changed from last meeting to now. As you can see, for 2007, we don't have any changes. Okay? For 2007, you can see that we don't have any changes from any time since the last meeting, and the same applies for 2008.

So we move to 2009. Item Number 1, the only change to this is that we actually closed this item. Guidance was revised in April of 2010 and was proposed to the ACMUI and provided via e-mail on January 26, 2011. And we consider this item closed.

Are there any questions?

(No response.)

No? Okay. Moving along, we are at Item

Number 5. This is actually a very old item where the ACMUI said they would create a Subcommittee that would include three members to review ICRP Report 103 and get back to Dr. Don Cool.

I have just been informed that the Subcommittee provided this information to Dr. Cool, which morphed into the ongoing interactions with the ACMUI and the ACRS on the staff's recommendations of how to proceed to examine the NRC radiation protection regulations. We will open a new action item if and when this action should arise from the Commission's direction.

Are there any questions?

CHAIR MALMUD: Are there any questions for Ms. Holiday?

(No response.)

MS. HOLIDAY: No?

CHAIR MALMUD: No. No questions.

MS. HOLIDAY: Okay. We will move on to 2010. Item Number 2, the Permanent Implant Brachytherapy Subcommittee will revise the draft Subcommittee report and resubmit it to the full ACMUI for an e-mail vote. The ACMUI will submit a full Subcommittee report to the NRC.

So the Subcommittee reported to the full

Committee, and the full Committee endorsed the report at the October 20, 2010, meeting, with the caveat that this is an interim report that may be revised in the future to consider additional input such as that that will be received from stakeholders at the public workshops that we will be holding in the summer.

NRC staff posted this report to the ACMUI public website on December 22nd of 2010.

Do we have any questions?

(No response.)

CHAIR MALMUD: If there are no questions, I understand that ASTRO will make a presentation today.

MS. HOLIDAY: They will. Thank you.

CHAIR MALMUD: And the memo has been distributed to members of the Committee.

MS. HOLIDAY: Yes.

CHAIR MALMUD: Thank you.

MS. HOLIDAY: Thank you. Moving to Item 13, Steve Mattmuller, Dr. Bruce Thomadsen, and Dr. Susan Langhorst offered to provide support to respond to the letter dated October 20, 2010, to Chairman Jaczko from Congressman Markey regarding patient release. ACMUI is currently still working on this.

VICE CHAIR THOMADSEN: This is Bruce Thomadsen. I don't know if we are still working on it. Since the Chair has responded already, I think that makes this Subcommittee completely moot.

MS. HOLIDAY: Okay.

VICE CHAIR THOMADSEN: Would the other members of that Subcommittee agree that we aren't still working on it, that it is closed as far as we're concerned?

(Several responses in the affirmative.)

MS. HOLIDAY: Okay. That will work for me.

Alright. Moving on, Item 17, ACMUI will provide a list of action items for NRC staff based on the recommendations provided in the Patient Release Subcommittee report. I also have this listed as an open item that the ACMUI is still working on.

MEMBER LANGHORST: This is Sue Langhorst. Yes, we -- I had offered to clarify action items. I think that Rob Lewis had asked for that, but have not done so yet, because I thought it would be helpful to have this discussion on that topic for this meeting, and also the workshops to include those in that consideration. So I consider that as still open and am willing to work on that.

CHAIR MALMUD: Thank you.

MS. HOLIDAY: Okay. We will on to 2011. Item Number 4, the ACMUI endorsed the Draft Final Safety Culture Policy Statement. The change here is that staff provided the proposal final policy statement for Commission consideration. The Commission held a meeting to discuss the policy statement on January 24th where Dr. Thomadsen presented ACMUI views on this policy statement.

The Commission approved the publication of the final policy statement on March 7th. Staff will make necessary changes, and then it has to undergo congressional review before it is published in the Federal Register.

Any questions?

CHAIR MALMUD: Any questions regarding that? There are none. Oh, there are. Mickey?

MEMBER GUIBERTEAU: When do you anticipate this will be published?

MS. HOLIDAY: I'm not completely sure. I have just been told that it is still undergoing review. But as soon as I know, I will let the Committee know.

MS. FAIROBENT: Dr. Malmud?

CHAIR MALMUD: Yes.

MS. FAIROBENT: May I ask a question?

CHAIR MALMUD: Please do.

MS. FAIROBENT: Lynne Fairobent, American Association of Physicists in Medicine. Sophie, you said that this is pending congressional review before being released? Did you mean Congress, or did you mean Commission review?

MS. HOLIDAY: I guess it would be Commission. I just -- my notes say the Congressional Review Act.

MS. FAIROBENT: Okay.

MS. HOLIDAY: Yes.

MS. FAIROBENT: Review against the Act, not that Congress is --

CHAIR MALMUD: Right.

MS. FAIROBENT: -- going to review it.

MS. HOLIDAY: Yes.

MS. FAIROBENT: Okay. Thank you for clarifying.

MS. HOLIDAY: You're welcome.

Okay. I think that's all I have.

CHAIR MALMUD: Thank you.

MS. HOLIDAY: Thank you.

CHAIR MALMUD: Are there any questions for Ms. Holiday?

(No response.)

There are no questions. Thank you.

MS. HOLIDAY: Thank you.

CHAIR MALMUD: We'll move on to the next item on the agenda, which is the Medical Events Subcommittee Report. Dr. Welsh?

MEMBER WELSH: Thank you, Dr. Malmud. Thank you to the members of the Subcommittee for assistance in preparing this report. It will differ from prior reports presented here at the ACMUI in that a request for some denominators, which allow us make more sense of this information, that request has been granted, and we are grateful to the NRC for providing this information through IMV.

So I'll go through these initial slides relatively quickly. The top number just shows you how many procedures there are in this country per year, so it's over a million. And among brachytherapy procedures, low dose rate prostate implants represent a large fraction, as do HDR, high dose rate afterloading procedures.

And one of the challenges that I will talk about again later is that the data provided is not categorized in the fashion that we would like it to be -- namely, according to 10 CFR 35 sections. So

you have to tease out the various components and then categorize them yourself. But, nonetheless, it was quite valuable to have this information.

We found that only in the 35.400 category there were about 25,000 of these brachytherapy procedures, the majority being prostate implant brachytherapy, and a smaller proportion being temporary implants.

As far as the 35.600 series goes, there are about 42,000 of these, the vast majority being HDR brachytherapy procedures, followed by about 8,500 Gamma Knife procedures, a huge number of diagnostic imaging procedures using radionuclides under 35.200.

And this slide is a little bit confusing. I'm talking here about 35.300 series, radionuclides with written directives. You can see on the bottom two lines, I-131 thyroid imaging is nearly half a million, thyroid therapy approximately 56,000, and then other iodine-131-based therapies, samarium, strontium, and others with written directives are the rest.

Out of all of those, there were four medical events last year, or in the fiscal year that we are referring to here. Three of them were I-131 thyroid patients. One was a neuroblastoma patient

treated with I-131 MIBG.

So out of 92,400, this represents an error rate that is quite minuscule. So it appears that we are doing relatively well in this regard as far as avoiding medical events.

Keep in mind that this is -- this denominator was provided through IMV, and it's 2007 and we're talking about 2010. So it's not perfect, but it does give us a good ballpark figure, a very good ballpark figure.

As far as 35.400 series, there were 27 events involving 27 patients. And this contrasts with 10 events in the prior period involving 114 patients.

I included the Y-90 microspheres here, but, as you know, they are in the 1000 category and probably shouldn't be lumped with these.

In the current period that we are discussing, there were 26 events involving 75 patients. So this is the 2010, and that means it is not very different from the year before. I included the Y-90 microspheres since we did that last year, last time, and that was a total of five -- one cesium-137 vaginal implant case in which the cylinder came out prematurely and was identified quickly. The

patient had approximately 76 rem to the thigh.

But then there were 69 patients who were identified having misadministration medical events with permanent prostate brachytherapy. Of these 69 patients, eight were categorized as overdoses, one an excess dose to normal tissue, one incorrect seed activity. And of the overdoses, one was retracted based on repeated post-implant dosimetry.

The rest of these were underdoses. Two of the underdoses were retracted and not felt to be true medical events. Upon repeat post-implant dosimetry, it was felt that the gland -- prostate gland swelled, and upon reevaluation at a later point when the swelling had subsided the final dose was within 20 percent of the prescription, of the written directive.

In one case, the D90 was less than one percent, so medically this would be a quite inadequate implant. But it was not categorized as a medical event, since 39 out of the 41 seeds were within the target and implanted within a few millimeters of the so-called isoline. The report states literally, "The seeds could have been placed in a better location." And the event was attributed to poor image quality. But upon review, it did not

meet the definition of medical event.

The majority of the medical events in this period were based on dose, specifically the D90, and the number of seeds outside the prostate. Review of these medical events leads one to again question the same thing we asked last time, which is, would these medical events be so labeled if we used a different definition, specifically one that was source-, strength-, or activity-based.

An interesting but important observation is that many, many of the implants -- the medical events during this reported time period were from earlier times. This tells me that many institutions are going back and reviewing their permanent implant brachytherapy programs and identifying medical events that might have taken place a number of years back.

And I can tell you that many more will be expected next year, because I used an arbitrary cutoff date of October 1, as we always do, and there were at least as many between October 1 and the present as in the prior period. And it seems that this is due to institutional reviews, and I think that many states are conducting such reviews. It's not just the institutions themselves.

There were approximately 25,000 implants

done according to the IMV data, and 26 events in 2010, and that means that we have an error rate or medical event rate of 0.297 percent. For prostate specifically, it is 0.33 percent, using the available denominator.

When it comes to the 600 series, you can see that comparing 2009 versus 2010 there is not a very significant difference at all. The Gamma Knife, the second one from the bottom, really no -- obviously no increase, and this might suggest that the Perfexion unit is not going to lead to an increase in medical events.

As far as the 600 events go, there were four HDR Nucletron events reported -- wrong catheter length in two cases, as well as software failure, incorrect treatment unit mode, incorrect contours entered.

The Varian source had four events -- wrong length, patient movement, possibly this was a wrong length as well, cylinder shift, and another with no information.

Three events reported in Gamma Knife due to incorrect coordinates entered, moving helmet, or the frame not fastened securely enough. Two events were in the Part 100 because of the new Perfexion

unit. One was wrong side treatment, and the other was a hard drive failure.

So as far as observations in the 600 category, wrong length seems to be the most important type of error. But when you put things in perspective, overall there were nine medical events out of 33,000. The rate is quite impressive at 0.027 percent.

Similarly, with Gamma Knife, three failures out of 20,000 procedures, 0.015 percent. And teletherapy had no problems.

And as the 1000 category goes, the two events in the Perfexion, with the Perfexion unit, four events with microspheres out of 1,400 treatments leads to a medical event rate of 0.3 percent, two each for the resin and glass spheres, one coronary brachytherapy event.

So as far as what we have learned through this exercise using the IMV surveys goes, we are very appreciative that we have the denominators now, but we have learned that there are some challenges with this. IMV focuses on a business -- with a business perspective, and it doesn't collect data by regulatory section of 10 CFR 35.300. So there is a little bit of an inconvenience in that regard.

They collect data based on site rather than procedure. From the raw data, it's not exactly clear where I-131 sodium iodine might fall, or where I-131 Bexxar treatments would be listed. And the radiopharmaceutical data was a composite of two years, and led to a little bit of confusion. But, nonetheless, we consider it quite valuable in providing a denominator that is truly close enough for demonstrating where we would need to direct further attention.

At least one of our Subcommittee members felt that unless there was change, a significant change, further reviews might benefit from focusing only on 35.400 to 35.1000 series.

So one might be able to conclude that brachytherapy in the United States is an extremely safe procedure, but one thing that we did observe is that in 2004 there were 192,000 or so prostate cancer patients treated; 41,790 were treated with permanent prostate implant brachytherapy, accounting for 22 percent.

But then, in 2009, after the series of medical events were reported and the negative publicity surrounding these events really was emphasized, in 2009 we had an increase in the number

of prostate cancer patients treated -- 219,000 -- but a significant decrease in the absolute number of prostate seed implants down to 17,490, and an even more substantial drop in the percentage.

Whether or not this is truly due to the negative publicity surrounding the medical events nobody will be able to say. It could be that alternative treatments have surfaced and caused prostate brachytherapy to decrease in relative and absolute numbers.

But one can't help but speculate, because so many people have said that this could very well happen. It did happen. Whether or not there is a direct correlation to the publicity in -- the negative publicity surrounding medical events is anyone's guess.

So I will conclude the presentation at this point.

CHAIR MALMUD: Thank you, Dr. Welsh. Are there questions for Dr. Welsh, or comments?

MEMBER ZANZONICO: Question?

CHAIR MALMUD: Dr. Zanzonico?

MEMBER ZANZONICO: The teletherapy, that is just for byproduct teletherapy? So that number doesn't reflect Linux and that sort of thing?

MEMBER WELSH: That's correct. I think it's only a cobalt-60-based teletherapy.

CHAIR MALMUD: Dr. Fisher?

MEMBER FISHER: Darrell Fisher. According to some of the physicians that I have talked to, the decrease in prostate cancer brachytherapy also may correspond to negative publicity on medical radiation.

MEMBER WELSH: Like I said, nobody will ever know the truth, because the DaVinci robot robotic surgery has surfaced in testing modulated radiation therapy. External beam radiotherapy is very safe and effective.

And so these things could be competed with prostate brachytherapy, but I personally -- and many others in the field -- do feel that prostate brachytherapy has experienced a decline, at least in part, because of the negative press surrounding the medical events.

CHAIR MALMUD: Dr. Guiberteau?

MEMBER GUIBERTEAU: Yes. As you mentioned, the IMV data is not perfect, but it is confusing even going back to the data, especially in terms of unsealed source therapies with I-131, since those requiring a written directive are not all

therapies. And I see you tried to pull them out here.

But I am curious to know under your slide here on page 3, on the I-131 thyroid patients using -- requiring a written directive, you have three medical events. And since there are only three, I am wondering if you could elaborate, first of all, whether those were all therapy patients, and then, two, what the events were.

MEMBER WELSH: Return to that slide. I might ask for assistance from our Subcommittee member who might --

CHAIR MALMUD: It's Number 9.

MEMBER WELSH: -- have addressed that specific section. But as I said at the start, there were -- we acknowledged that there are some challenges with IMV data and pulling out the subcategories from this raw data.

CHAIR MALMUD: Number 9, Slide Number 9.

MEMBER GILLEY: Debbie Gilley. This was the section that I wrote on, and I do not remember what those three were. I am making the assumption they were thyroid ablations for thyroid cancer, but I can't, without looking at the raw data, tell you that. Maybe you have the raw data, Donna-Beth?

CHAIR MALMUD: Would a member of NRC staff have those data? Dr. Howe?

DR. HOWE: I don't have the raw data with me, but I can get it. It seems to me many of the cases were two capsules and only one was given. And I believe they were the therapy. There may have also been a diagnostic that ended up getting greater than 30 microcuries, so I can check on that later.

CHAIR MALMUD: Thank you. Dr. Thomadsen, did you say you had this?

VICE CHAIR THOMADSEN: I am looking.

CHAIR MALMUD: Oh, okay. Dr. Guiberteau?

MEMBER GUIBERTEAU: I have a suggestion. No one likes big, committees that are too big, but I think it might be helpful since most unsealed source therapy in the United States is performed by either diagnostic radiologists with nuclear medicine training or nuclear medicine physicians that perhaps it would be helpful to have someone with that background, a physician with that background, either as a consultant to the Committee, so that they can be understanding -- starting to understand these analyses now that we do have the IMV data, and to follow it, because it is confusing and we want to make sure that in terms of those actually using this

that we can come up with some information and our rationales for any changes in our policies.

MEMBER WELSH: Well, if I could respond to that --

CHAIR MALMUD: Dr. Welsh?

MEMBER WELSH: -- I would certainly welcome any additional help from someone with expertise on this Subcommittee, and nobody, of course, wants the Subcommittee to get so large that it becomes unwieldy. But I don't think that the addition of an individual with such expertise would cause that.

This slide, however, suggests that since the number of medical events in the 200 and 300 categories is just so low that one of the Subcommittee members suggested that we focus only on the section where the real action is.

And I guess if you look at the numbers, the real action might amount to 0.01 percent or higher, and those numbers are so low that, in my opinion, the difference between 0.00001 and 0.001 is not different enough -- significant enough that we should drop a section or two.

So I think that we could continue to focus on the 300 series, and I would welcome

additional assistance from somebody with expertise in that area.

CHAIR MALMUD: If I may, there is a member of the Committee who still performs I-131 therapy on a regular basis, and he would be happy to review each case individually if they are brought to his attention. That would be myself. Is that permissible, for the Chair to engage in such a role?

MR. LUEHMAN: You can be a member of a Subcommittee.

CHAIR MALMUD: I'm willing to serve as a reviewer of one, which is what you are asking for. Am I correct?

MEMBER WELSH: Yes.

CHAIR MALMUD: I would be happy to serve as a reviewer of one to just screen those cases individually and give you my impression as to what happened. I'm more than happy to do that.

MEMBER WELSH: And if I might go back to the slide and ask the individual on the Subcommittee if he or she feels strongly about that last bullet point. I think it was Mr. Mattmuller.

CHAIR MALMUD: Dr. Welsh, which bullet point are you referring to?

MEMBER WELSH: The last bullet point here

on this slide.

CHAIR MALMUD: Slide 27?

MEMBER WELSH: Which is that further reviews should really focus only on 400 to 1000. I personally don't think that we need to drop anything here, but I can understand that when we're talking about numbers that are so extremely low that it might not be worth the exercise.

CHAIR MALMUD: If I may, Dr. Welsh, I think that what has happened, what possibly has happened, is that a single incident consisting of perhaps as many as 90 cases with a single institution has cast a pall over brachytherapy. And it is not a matter of statistical reality, but a matter of public perception.

My own impression, being in Philadelphia, the city in which this occurred, is that a number of patients have chosen not to select brachytherapy as their form of therapy.

Therefore, we would be doing a continuing public service by monitoring these activities, and the NRC, of course, by enforcing whatever regulations are appropriate to assure that these kinds of incidents don't occur, because a single incident can result in patients not choosing a therapy which would

otherwise have been very therapeutic and useful for them.

So that, in a sense, we are dealing with a perception rather than reality, but perception becomes reality in the minds of a public which is not highly educated to the risks and benefits of many of the procedures that we perform in medicine and surgery.

Therefore, it is my impression that it is a worthwhile effort to continue to track these things in the manner in which you have begun to do already on a regular basis. Regardless of the small number of incidents that occur, these are almost like airplane accidents in which a single accident will have an effect upon people's willingness to travel by air in some instances.

But in this case, we are dealing with patients who are not necessarily choosing an optimal therapy when it is offered to them, because of fear of what they have read about one institution and its results.

So I would think that that which you have presented to us is extremely useful and can serve the public best if we continue our effort and the NRC continues its effort. But, of course, we want to see

and hear from ASTRO with regard to its comments with respect to what policy should be employed in the future if its opinion differs from the opinion so far expressed by the Committee as a whole. Does that resonate with you?

MEMBER WELSH: I fully concur with what you've said; with the addition that it is not only limited to therapeutic procedures. If a diagnostic procedure starts to get a reputation that it could in some way be risky, patients would shy away from that as well, and, therefore, I would favor including all of the items that we included in this particular year's exercise in future exercises.

CHAIR MALMUD: Thank you. I think there are other comments from members of the Committee. Dr. Thomadsen?

VICE CHAIR THOMADSEN: Just in response to Dr. Guiberteau's question, of the four iodines, three were therapeutics. One was a patient who had received iodine therapy and was supposed to have a diagnostic scan as follow-up but got, by mistake, a therapeutic dose. So, all of them were therapeutic doses. One was a peculiar one.

MEMBER WELSH: Thank you.

CHAIR MALMUD: Thank you. Was there

another comment? Yes, Dr. Suleiman.

MEMBER SULEIMAN: I think maybe if we took a step back and look at things a little bit more globally, number one, I am not so sure the negative publicity has had the impact that we perceive. I think you've got a lot of alternative modalities, technologies, protocols, that are competing with a lot of these procedures, some of them non-radioactive.

The other concern that I have had for many years -- and I think I explained it to the Committee before, and I'll restate it again -- radio-labeled therapeutics or radio-labeled drugs, the dosimetry associated with them is much different than the dosimetry associated with external beam or brachytherapy where you can pretty much trust the precision and accuracy of what you are measuring and how you define a medical event.

We are entering an era where you are getting a lot of hybrid protocols, you are getting a lot of hybrid modalities, you are getting diagnostic, and you are getting therapeutic. There is real potential there for confusion by the community using it, and I -- so this business about a diagnostic being used as a therapeutic, or whatever, doesn't

surprise me at all. I think you may see more of that in the future if the practitioners or the users of these products aren't, you know, more careful.

So I definitely think we should look at a broad scope, but at the same time, I'm concerned in that I'm still not very comfortable with the whole medical event definition, because what we are seeing now, a lot of the high doses are -- a lot of the imaging procedures, both radioactive and non-radioactive, radioactive material, and then you may be using X-ray and other modalities, are associated with the heart.

And there was a meeting -- I was at the American College of Cardiology meeting, I believe, and I think one of the papers talked about some patient receiving 15 exams. Now, this doesn't address this -- it's a little bit out of scope of the medical event, but it's an issue of public safety and concern.

There needs to be more emphasis on keeping track of doses, especially for therapeutic patients where they may be getting a pretty sizeable dose from one procedure, and they may get a dose from another procedure. And if they're sick, they may go into different hospitals, and so I -- we may be

getting into an area where you may be seeing some toxicity issues coming.

But unlike SCID where you may see the damage, internally you don't. We have had -- this is public information -- we have had clinical trials where patients -- subjects have died because somebody didn't do the dosimetry right and the wrong organ received a certain amount of dose. So the level of science in the unsealed sources is nowhere near.

And when you talk about radiation therapy, people assume that it has a level of precision associated with people like, you know, our medical physicists in the field who are doing the therapy calculations. But in terms of the unsealed sources, most of the effort historically has been on the diagnostic side.

So let's not focus so much on the regulatory criteria. I mean maybe we need to look at this a little bit more carefully if we are concerned about the public

CHAIR MALMUD: Another comment. Dr. Van Decker?

MEMBER VAN DECKER: Yes, just a couple of comments. Number one, I wanted to thank Dr. Welsh for his persistence in getting some type of

denominator here. I think that, you know, that is always useful in getting a sense for things, and I think the IMV data is probably the best you've got because it goes across all age groups.

I would also point out, obviously, that if you're looking for individual CPT codes -- and since this is, no matter how you look at it, only going to be a gross denominator, obviously, to CMS and HOP's databases by CPT code for each of these things, maybe give you a relative decision breakdown of where therapy is in the iodines versus not -- you know, something to kind of keep in mind.

As far as the comment on, you know, diagnostics versus, you know, high group therapies, you know, I think I would just take us back to the step of what this process is all about. I mean, all we are really looking for here is a review of things that could allow us to see systems, issues that would allow us to create safety.

So I think that, you know, the goal of the Committee is to just have an eye on what is safety, and so I think looking at all of the different realms from 100 on up is not unreasonable, because you never know when a system's issue might show up as a background noise.

And so, you know, I think that, you know, the goal is to know what those individual things are, because even if one case shows up, as Donna-Beth Howe has proven to us over the years, if it's one case where there is a dramatic system error that could be propagated to the stakeholder community through this group, then that is something that creates a positive impact for safety down the line.

And so I think that we are looking for individual system safety issues, plus some sense for what is the background noise of what is going on, which is, you know, the reality of choosing one or the other. And so I would just try to put that into context in -- you know, into the context that we are all here trying to make sure that, you know, we do what's right for patients and get some good outcomes as well. And, you know, these are all useful techniques in doing that in one way or the other.

CHAIR MALMUD: Thank you, Dr. Van Decker.

Are there other comments regarding this issue?

(No response.)

I would just add, if I may, that the regulatory environment is critically important, because it can govern the availability of procedures

to patients, since physicians or other practitioners who are hesitant to use a modality because of ambiguous regulations will withhold it, to the detriment of the public.

At the same time, the adherence to regulations is critically important, because it reassures the public of the safety of that which is being provided. So that the reason for the regulations is very clear, and it affects both the providers and the patients and is something that we are entrusted with monitoring, with the NRC, and which we take very seriously.

I think if I caught the undercurrent of your comment it is that what we need are clear, practical regulations, for the benefit of the public as the recipients of this, and to reassure the providers that they will not be unjustly punished or criticized for therapies that are correctly applied.

MEMBER WELSH: I fully agree with what you have just said, Dr. Malmud. The area that still stands out in this exercise is the area that stood out last year -- namely, permanent implant brachytherapy, specifically, prostate seed implant brachytherapy.

And to underscore what you have just

said, the definition remains a little bit confused in the opinion of many, and, therefore, institutions and states have gone back to review cases going back several years and have discovered that strict application of this definition is leading to a surprising number of implant -- medical events in implants that would seem perfectly acceptable on the surface.

But when you adhere strictly to this current definition, many implants that appear medically acceptable and maybe even effective, certainly safe, are labeled as medical events.

And that's why I said that next year we could be in for a disappointingly large number of these, simply because this review process is going on at many institutions in many states using the current definition, which I know is the subject of great discussion and debate, and I think we will continue that discussion right after my presentation.

CHAIR MALMUD: Thank you again, Dr. Welsh.

MEMBER MATTMULLER: Dr. Malmud?

CHAIR MALMUD: Yes, excuse me.

MEMBER MATTMULLER: Steve Mattmuller. Again, I really appreciate your comments on

perception versus reality, because that often trips us up -- so often. And I had planned to make this comment later, but I think it might be appropriate for now in dipping through the backgrounds on medical events, especially in regards to brachytherapy.

And this comes from a SECY document of 10-0062. In regards to what a medical event is -- and to read from this -- they are designed to detect events that have the potential to harm -- I've lost my place, sorry -- to harm the involved patients. And the goal is to identify possible problems before they rise to that level.

So in dealing with perception versus reality, some of these get identified as medical events, and I'm sure the public perceives that as this is bad, something awful has happened to these patients, where in fact especially in the prostate we know that's not the case.

So I think through all of our discussions I think that is an important aspect to how the NRC looks at a medical event. It has the potential. It's not that something bad has happened potentially -- or I should say something unusual during the administration occurred. Potentially there is harm, but we're not saying there is harm; we're just

looking at it to make sure things remain as safe as possible.

Thank you.

CHAIR MALMUD: Thank you, Mr. Mattmuller.

Other comments regarding Dr. Welsh's presentation?

(No response.)

Thank you.

We'll move on to the next item on the agenda, if we may, and that is the Purpose of Rulemaking Meeting, which Mr. Fuller will provide for us.

MR. FULLER: Thank you, Dr. Malmud. Again, my name is Mike Fuller, and I am the Team Leader for the Medical Radiation Safety Team. I want to take just a few minutes and talk about this particular meeting, and take just a moment to talk about how this meeting is just a little bit different than some of the other meetings at the ACMUI.

In Staff Requirements Memo SECY 10-0062, the one that Steve Mattmuller just referred to, the Commission directed the staff to hold a series of stakeholder workshops. And so we are complying with that in a certain way, and also in accordance with our SECY paper 11-0035. We informed -- the staff

informed the Commission that it planned to devote this meeting to 10 CFR Part 35 rulemaking activities.

So, and our direction from the Commission to hold a series of workshops, we are dedicating this particular meeting to 10 CFR Part 35 rulemaking activities. And in addition to that, we will have two more workshops, currently scheduled -- I should say tentatively scheduled for the middle of June and more developments on that, more discussion on that later.

We have been working very diligently and very hard recently to try to get these dates and locations nailed down, and we should have some very good news on that shortly. So that's what we were trying to do.

Also -- go to the next. Okay. So over the course of the next two days -- today and tomorrow -- the ACMUI members and members of the public will have the opportunity to provide the staff with their comments, concerns, and insights on the key topics that we will be discussing.

Now, in my earlier, more formal remarks when we opened the meeting, I mentioned the fact that we would like to have consensus whenever possible. And that is still the case. However, for purposes of

this particular meeting, we are very interested in the comments, concerns, and issues that individual members of the ACMUI would like to provide us with. But if, in fact, the Committee would like to provide us with a consensus position, then we would very much welcome that as well. It's just not, you know, absolutely the focus for this particular meeting.

And so our primary position, the staff's primary objective, is -- for this particular meeting is for us to listen. So over the course of today and tomorrow, we will be having various members of our staff come and provide you with a brief summary of the issue that we would like to hear about, or hear from you about, and provide you with whatever status we might have on that, where we are in the rulemaking process, if we are actually in the rulemaking process yet on that.

But, again, our focus is to listen primarily to what your comments are. And, of course, at Dr. Malmud's discretion, if you want to open it up to members of the public, we would very much welcome those comments and concerns as well.

After me, Neelam Bhalla and Ed Lohr from our Division of Intergovernmental Liaison and Rulemaking will be providing sort of a brief overview

of all of the expanded -- of all the issues and topics that are being considered currently under the expanded Part 35 rulemaking activities.

And then, after that, for the balance of the meeting, we will discuss four topics in particular. They are permanent implant brachytherapy, the extending of grandfathering to certain certified individuals, and some rulemaking activities related to preceptor attestation requirements, and then also we will have a discussion on the public dose limits and the need -- potential need for rulemaking on public dose limits for released patients.

So those are the four key topics that we will be trying to focus this meeting on. However, as I said earlier, Neelam Bhalla and Ed Lohr will be providing you with an overview of many other topics that are currently being considered for rulemaking. And if time allows -- and, again, at the discretion of Dr. Malmud -- we may open -- maybe late tomorrow open those up, some of those other topics up if people would like to provide us with their insights and their comments on those as well.

So with that being said, again, we are here to listen for the most part, and we are prepared

to answer questions on these topics to clarify issues, and so forth. But we really want to hear your views.

And with that, are there any questions for me at this point about process and what we plan to do or hope to do over the next two days?

CHAIR MALMUD: Sue?

MEMBER LANGHORST: Mike, we are focusing on four issues in today's -- or this week's meetings. The workshops, you will talk about all of the issues, or will they only focus on these four also?

MR. FULLER: We are planning to focus on the same four issues. And just to be clear, the Commission directed us to hold a series of workshops for the purpose of gaining stakeholder input, public stakeholder input on the medical event definitions as it relates to permanent implant brachytherapy.

Because we knew we were in the process, in the early stages of rulemaking activities for what we have been referring to as our expanded Part 35 rulemaking, which has 28 or 30 topics, we looked at those to see which ones would either be of the most interest, the most controversial perhaps, or the ones that had gotten the most attention in the past.

And recognizing that there is limited

time to have a facilitated discussion on these topics and to have them be really worthwhile, we are going to limit those to those same four topics.

CHAIR MALMUD: Jim, you had a comment?

MR. LUEHMAN: Just to -- I mean, I think that one of the purposes of this discussion with the Committee is that, as Mike said, we have chosen four which, based on public -- previous public comment, interaction previously with the Committee, or interaction within the staff, that we think are going to be the primary focus of those workshops.

But if the Committee, in its wisdom today, wants to tell us that we -- that there is probably another one that is probably one that we should be ready to highlight, I mean, I think that that will make those upcoming meetings/workshops that much more beneficial, that we will be really prepared to talk -- we think we are prepared to talk about the issues the majority of the medical community and stakeholders want to talk about.

But if there is one -- if there is an issue buried in there that we hadn't anticipated, hopefully we can -- we can, you know, tease that out today, so that the staff will be better prepared for what we thought was, you know, maybe a non-

controversial issue in those 28 that might be more controversial or more complex than we anticipated.

MEMBER LANGHORST: Okay.

CHAIR MALMUD: Thank you. Dr. Van Decker?

MEMBER VAN DECKER: Would you be willing to comment a little bit on timeline in your mind, A? B, whether you see these workshops more than being a couple in June, and whether there are some coming in the fall? And the second main question is the involvement of the Agreement States in all of this, because we know the three-year timeline to move things through the Agreement States and what that really means in the long run for trying to get things to happen in the nation.

MR. FULLER: Well, concerning the timeline, that issue is still before the Commission as far as a decision goes. We have a paper up there now that they have not voted on. I do know that Neelam and Ed are prepared to talk a little bit about, you know, what typically -- what requirements there are for rulemaking as far as the timeline.

As far as any additional public meetings, stakeholder meetings, the meetings we are discussing or planning to have in June are early in the process

before there is a proposed rule. And, again, Neelam and Ed can make sure I am being -- saying the right things here.

But my understanding is, is that these are an opportunity for us to gain early comments and early insights from the public and key stakeholders. And we are planning to have participation by Agreement States in these workshops. I probably should have mentioned that earlier.

The real challenge for us, to be real clear, has been getting contracts in place for putting these workshops on to help with the logistics, and so forth. And we think we are very close. We have actually awarded a contract within the last couple of days, and we have had some good meetings with our contractors. So we are moving forward. We should have some dates and locations very soon.

MR. LUEHMAN: And the other thing I would just add to what Mike said is we are also very cognizant that there is a lot of professional -- the major professional societies that have their meetings during the late spring, the summer, and the fall. And we have been in our planning, though we don't -- can't bring forth the dates, the specific dates

today, in our planning we have been very cognizant of those types, and we are trying to work around, as best we can, all of those dates.

MR. FULLER: And the other thing I will mention, too, is that as soon as -- that has been our big, big hang-up. As soon as we have the dates and locations nailed down, then we will be working extremely hard to do, you know, outreach. And we have already outreached to some organizations on this and had some informal discussions with different folks in the states. So, again, hopefully we will have some really good news on this just in a matter of days.

The other thing, though, to answer your question, Dr. Van Decker, with regards to opportunities for additional public participation, again, this is all pre-proposed rule, pre-rulemaking, or pre-drafting of rule language. Once there is a proposed rule drafted, then we will follow our normal process for public participation in that as well.

So this is -- this two days, and the workshops in June, are opportunities for the staff to hear from key stakeholders and co-regulators and everyone, members of the public, to get early insight into the types of things that we need to be focused

on, such that when we do get busy writing proposed rule language that we have that information available to us and we take that into consideration.

CHAIR MALMUD: Thank you. Ms. Fairobent?

MS. FAIROBENT: Dr. Malmud, thank you. Lynne Fairobent with the American Association of Physicists in Medicine. I just have two comments, if I might, to the presentation that we just heard. First, to consider the ACMUI meeting and public workshop to discuss rulemaking activities, I find very ironic.

To bury that type of statement in a SECY paper to the Commission and saying you are considering this meeting a public workshop to discuss these, but not to present it that way in the March 29th Federal Register announcing this meeting, I think is indicative of why you do not have a larger public here today.

Second, NRC continues to schedule public workshops with less than eight weeks' notice to the community that is being impacted. We have in the past asked for a longer time. To schedule two workshops of this significance on this particular rulemaking, even if you are focusing only on four -- maybe the four most significant items of the 28 in

the draft rulemaking, is insufficient notice to the community to adequately present and participate in order that NRC can receive the best input from the public early on in the process.

CHAIR MALMUD: Thank you for your opinion. May I ask what you believe would be more optimal notice than eight weeks?

MS. FAIROBENT: We are being told by our members -- and I am hearing through the community -- that it takes three to six months notice in order to be able to schedule time off and away from the office in order to participate adequately in public workshops.

And particularly, scheduling public workshops in the middle of major scientific professional societies' meetings when many members are only being allowed, if at all possible, to travel to one professional meeting in a year, really is impacting the community to provide the adequate input that the NRC might need as they promulgate regulation.

CHAIR MALMUD: If I may, we of course have no control over the travel budgets of the members of any professional organization which may want to send representatives to a public meeting. So

that's not an issue that we can deal with.

However, the issue of timing is something that we might be able to address to make -- to establish the meeting at a time when the calendar does not show a major scientific meeting conflicting with these presentations. Would that be a reasonable approach for us to take with respect to your concerns?

MS. FAIROBENT: I think that we would appreciate any help at all in obtaining further notice about rulemakings. This happened with the Part 20 rulemakings. Again, it was reflective of NRC's contracting procedures to hire facilitators. And I think continuing to compress the community such that they can provide and participate really is providing a negative impact. That is my view.

I'm hearing it from the community. I don't know if anybody else has heard it from any of their members, but I'm certainly hearing that at meetings, and at both professional society and at public workshop meetings.

CHAIR MALMUD: Thank you for communicating that to us.

Dr. Welsh?

MEMBER WELSH: Jim Welsh. I agree with

the opinion of Ms. Fairobent that we just heard from the AAPM. And I suspect that if we are considering this ACMUI meeting to be part workshop, that we are not going to resolve all of the issues during this one meeting, and this might present an opportunity to announce that in six months when we have our next ACMUI meeting it could also be a workshop, if this particular session works out to our satisfaction today and proves to be a viable venue. That way, we could continue our discussion with all of the members involved and with adequate notice to AAPM and other stakeholder organizations.

CHAIR MALMUD: Other comments? Dr. Suleiman?

MEMBER SULEIMAN: I think maybe the workshop confuses. I think we have got enough issues to discuss. I think it sounds like you're scheduling open public workshops in the future, so I don't think anybody is going to be denied an opportunity to participate.

I absolutely agree with Lynne. I think there are too many meetings by too many groups. I have trouble all the time -- I don't know about the rest of you, but I do -- and I can't get to these meetings. I can't prepare for them. And I think

it's an indication of our times. Sometimes a lot of information is flowing too fast for people to digest it. I think that, to me, is a more palpable concern.

But aside from that, I think let's have our discussion, and you'll have more discussions in the future on this, so you will give other stakeholders an opportunity.

But I absolutely agree. I usually don't like -- for meetings where I am asked to participate; I used to say six to 12 months. Forget that. That doesn't seem to be the case at all anymore, so it's difficult. A little bit more lead time would be nice.

CHAIR MALMUD: So you are in favor of a longer lead time of about six months?

MEMBER SULEIMAN: Well, that's just -- the longer, the better for me.

CHAIR MALMUD: I have a question for NRC staff, and that is, when is the effort -- these workshops supposed to be completed?

MR. FULLER: Well, currently we have tentative dates that are the second and third week in June and -- the second week of June and the third week of June. And we -- I guess we can share the frustration, because we have been working very, very

hard to try to get these dates nailed down for a considerable amount of time. And I will just leave it at that.

However, if the Committee would like to provide us with a recommendation that we postpone them or do something to allow more time, you know, we would be happy to receive that. But keep in mind that what we have tried to do -- the real challenge for us has been to account for the various professional society meetings and not to have them at the same time, to try to have it in different parts of the country, so that folks who might be at one at a time near when we are scheduling ours could have at least some time off in between.

But also, we are trying to work with a rulemaking schedule that is a multi-year schedule. And if we delay the workshops very much, it will have a real impact on when we can actually get the proposed rules out and meet those deadlines and those milestones.

So we do share in the frustration. We agree that it would be better to have more lead time to make our announcements, and we have been working as hard as we can to get as much time in advance as possible, and we have had our challenges.

CHAIR MALMUD: Are there further comments regarding this issue?

MEMBER MATTMULLER: This is Steve Mattmuller. I would suggest perhaps trying to piggyback some of these workshops to the professional meetings to lessen the burden on the travel funds for some of these people, because then it is much easier for them to schedule and to attend the professional meeting and then stay for another day or two for the workshop meeting than to make two separate trips.

I know last fall I became a volunteer for a workshop, because it happened to piggyback onto an ACMUI meeting here in D.C., and so -- but I came as a member of the SNM, and they said, "You're here, you know, can you do this for us?" And so it worked out in that regard, because the professional organizations have travel constraints also.

MR. FULLER: And I do appreciate that comment, and we have had -- we have had that comment, and we have also had the exact opposite comment. And that is that while it may seem to make sense for travel dollars, away-from-the-office time is something that is also something that people had a hard time with.

So we have actually tried to learn from

experience that organizations with NRC had done this very thing, and there was a tremendous amount of negative feedback for piggybacking.

But we -- again, I do appreciate that comment, and it is something that we did wrangle with early on.

Just to let you know, we are in the process now -- we did finally get a contract awarded for doing -- setting up these particular workshops. And we had -- late last week we had our kickoff meeting with the contractor, and they have been directed in their focus and they have assured us that they are going to work on nothing but nailing down these locations and these dates.

And hopefully within a matter of days we will have something that we can then work very, very hard to get out the word, recognizing that eight weeks is not very much time for people to prepare. I understand that, and we are going to try to work with that as best we can.

Also, keep in mind that we have had -- the focus of this is on permanent implant brachytherapy. We have had a pledge on the part of -- at least on ASTRO's part that they are willing to participate, although I know we have probably made

things hard on them as well.

And so we are still hopeful and still optimistic somewhat that we can have a fruitful discussion on the issues at these workshops. But, yes, it has been a real challenge for us.

MR. LUEHMAN: I would just like to add, Dr. Malmud, just quick two things. One is that, as Mike said earlier, I will reiterate, I mean, if the collective wisdom of the Committee is that we need to -- that we should move it out further, if that is the recommendation, then, you know, we will take that under consideration.

But as Mike also said, that this is -- you know, this process has only got so much time in it. And if we want to have stakeholder meetings before the rulemaking, then if we put the rule -- if the put the stakeholder meetings out too far, we are going to then start impacting the rulemaking schedule, which I think that is going to get negative reactions from stakeholders, too. So there is -- you know, it is sort of a zero-sum gain in that regard.

The second thing I would say is, as far as characterizing this ACMUI meeting as a workshop, again, I appreciate Dr. Suleiman's comments on -- you know this isn't really a workshop. I think that what

we wanted to do is to be informed by the Committee as to the subjects, whether we are hitting the mark, or whether the subject matter that we see as the main subjects for the workshop, if we are in the correct place.

To the extent that the public wants to offer comments on that, or on the particular subjects, at the Chair's discretion, that's fine. That sort of gives us a leg up. But, really, we intend to -- the two meetings that we intend to hold away from Rockville are -- with a lot more notice are really going to be, if you will, the two true workshops that we are going to have before them.

I think it's inescapable that, you know, if we start talking about those subjects today, to the extent that they are on the agenda, that we may get public comment, and that would put us that much further ahead. But, you know, we may also get comment from the Committee that we haven't got all the right subjects or -- and that's why we are here to listen.

CHAIR MALMUD: Dr. Langhorst.

MEMBER LANGHORST: Mike, how can the public interact with the workshops, and how -- what are other avenues for the public to interact on this

pre-rulemaking effort?

MR. FULLER: I appreciate that question. Not only are there going to be workshops that will have facilitated discussions on these various issues, but there will be a webinar where folks will be able to see and hear the presentations, and be able to see the slides, and hear the audio discussion while they're going on. And there will be an opportunity for people to participate from remote locations, as well.

MEMBER LANGHORST: Okay. Are there are other avenues for people to participate, or organizations to participate in this pre-rulemaking effort, other than those two workshops?

MR. FULLER: I'm going to yield to one of our rulemaking experts who can, perhaps, answer that question.

MS. BHALLA: Yes. What we also plan to do besides the workshop is post the draft rule text for most of the items which are out there, so we'll be very -- we'll put what the understanding is, what the draft rule text will be. Basically, it'll be asking for comments. But when we do the proposed rules, we will not be addressing those comments comment-by-comment, which we generally do at the

proposed rule stage going to the final rule. But we will take into consideration what the comments will be on these proposed rulemakings.

CHAIR MALMUD: Thank you, Ms. Bhalla.

MEMBER LANGHORST: Thank you.

CHAIR MALMUD: May we assume, though, that we have heard from a member of the public that these meetings should be scheduled no sooner than six months after the announcement? Am I correct in having heard that suggestion?

MS. FAIROBENT: Lynne Fairobent. Dr. Malmud, I said typically, we're hearing that it takes at least three months, so three to six months would be optimal for people for planning, and six to eight weeks is very tight scheduled. We're about eight weeks out now from the second week of June. The Federal Register Notice doesn't appear for another two or three weeks with the final dates in it. We're getting close to less than six weeks notice.

Perhaps, and I believe you me, I don't want to drag out the rulemaking process any longer. It's been dragged out enough, but maybe having the two workshops a week apart, if someone can't make the second week of June, they're probably not going to be able to make the third week of June. So, if there's

more time between the two workshops themselves, you may be able to pick up more people, even if there's less than three or six months notice.

CHAIR MALMUD: Thank you. We've heard a suggestion.

MR. FULLER: Okay.

CHAIR MALMUD: Thank you. Are there any other issues with regard to the item on the table at the moment? Ms. Bhalla.

MS. BHALLA: I, also, just want to bring it to the attention, since there was a comment with regard to an announcement, in the Federal Register, even though, for example, this meeting was the meeting announcement, well, we could not -- in the Federal Register, they have their own rules, so we could not put it under Meeting Announcements, so it was issued under proposed rules. And that's just a rule of the Federal Register, itself. So, therefore, when we sent the list of -- through the list of announcements, we were able to characterize that this meeting would -- it is ACMUI's meeting, so the announcement was for the meeting. However, it was announced through the proposed rule section. So, I will -- even for June meetings, or whenever those meetings will be, please look for the announcement

under the proposed rules, and not in the meetings. And just the way the Federal Register works. So, just a little note.

CHAIR MALMUD: Thank you for that information. Any other comments from either Mr. Fuller or Mr. Luehman? If not, then we'll move on to the next item on the agenda, which will be that of Ms. Bhalla and Mr. Lohr; that is the Overview of Part 35 Expanded Rulemaking.

MEMBER WELSH: Dr. Malmud.

CHAIR MALMUD: Yes, this is a question from Dr. Welsh.

MEMBER WELSH: To finish up our last discussion, I'm wondering if it might be appropriate to propose including in the next ACMUI meeting some dedicated time for workshop activities, so that we might have sufficient notice that would, perhaps, address the question that was just raised. And this could be in addition to the ones that are already being scheduled in June, not to replace them, but in addition. But, as we heard, with less than six weeks notice, some people or members of stakeholder societies might not be able to attend. ACM, my members might not be able to attend, but if we know six months in advance that an hour, or two, or three,

or whatever might be appropriate for the be workshop-related event, we could put that on the agenda for next time to give adequate notice.

CHAIR MALMUD: Dr. Welsh is suggesting that our next ACMUI meeting, which will be scheduled in the fall, would be an opportunity to incorporate some hours of a workshop. What's NRC Staff's response to that suggestion?

MR. FULLER: Well, I can -- I think the Staff's position, as always, is that we are -- for the ACMUI, we're here to support you in these meetings, so if you would like to have some time dedicated in the fall meeting to continue the discussions, to continue the opportunity to provide the Staff with your comments and insights on the various things that are undergoing rulemaking, I don't believe, and I'd have to defer to the rulemaking experts, but I really don't believe, at least on the key topics that we're focused on right now, that there's any reason why we couldn't continue to hear from the ACMUI members, the ACMUI as a Committee, or individuals who represent various professional societies, and so forth. To me, it sounds like it would be another good opportunity for us to hear from our key stakeholders.

CHAIR MALMUD: The Chair would like to entertain a motion, therefore, from Dr. Welsh, that that be incorporated into the next meeting, and see what the members of the Committee feel about it. Would you care to make that motion?

MEMBER WELSH: So moved.

CHAIR MALMUD: So moved. Is there a second to Dr. Welsh's motion?

MEMBER VAN DECKER: I have a question.

CHAIR MALMUD: Before the question, it's seconded by Dr. Thomadsen. Now, we have a question from Dr. Van Decker.

MEMBER VAN DECKER: I guess my mind set would be hearing what you believe that the time line for the proposed draft rule is going to be, and how long -- four more months of waiting over the summer is going to delay things. There are pieces of this that, obviously, have been talked about now for several years since the rule came out, and everything that slows things down as the yin and yang of life, but discussion is good, just depends on what the timing --- the approach timing was to start with, from a brachytherapy part of the pool, anyway.

MEMBER WELSH: I'd like to respond.

CHAIR MALMUD: Dr. Welsh.

MEMBER WELSH: I would certainly hope that we would not need to have another stakeholders meeting in six months. But given that this has dragged out for so long, and it's so controversial, in all reality I suspect that we will not have full resolution following the June discussion. And, therefore, it might be reasonable to have something on the schedule that would be easily postponed or cancelled. And we could certainly find alternative topics to discuss in this Committee, but if we do have something reserved, as far as specific time, if we do not resolve this situation in June like we hoped, at least we will have a schedule to follow discussion that people will be aware of, the public can be aware of.

CHAIR MALMUD: Thank you. Other comments with regard to the motion on the table? That's the motion of Dr. Welsh to incorporate some hours in our next meeting, which will be in the fall, for the workshop? Mr. Mattmuller.

MEMBER MATTMULLER: Yes. I peeked ahead at their Integrated Plan, and the Staff hopes to consolidate comments from all the workshops July through September of this year, our next meeting would be in October. And if you look further down

after Proposed Rules, they still have three public meetings, so I think that's going to be ample opportunity. I don't know if we need to add one more opportunity at this point for public discussion.

CHAIR MALMUD: Are you speaking in favor of Dr. Welsh's motion, or against it?

MEMBER MATTMULLER: Against it.

CHAIR MALMUD: Against it. Because you feel the work will have been completed by September.

MEMBER MATTMULLER: I think the first draft will be completed by September. And then after that with the proposed rule, they still plan three public meetings to comment on the proposed rulemaking. So, I think there's going to be ample opportunity to guide the NRC in this regard. So, yes, I'm against it.

CHAIR MALMUD: Are you concerned about the issue raised by the member of the public with regard to adequate notice for these meetings?

MEMBER MATTMULLER: I am sensitive to that.

CHAIR MALMUD: That's what's triggering off this consideration --

MEMBER MATTMULLER: Yes.

CHAIR MALMUD: -- for incorporating an

additional hearing for members of the public to participate in the workshop. All right. Other comments from Members of the Committee? DR. Suleiman.

MEMBER SULEIMAN: I stepped out for a minute. These are not new issues.

CHAIR MALMUD: Correct.

MEMBER SULEIMAN: These didn't come to us fresh, never heard of before. So, these are issues that have been out there for a long time, so I think we should take that into consideration. I think these issues -- I'd be surprised if we get any new perspectives on this. It's just going to be a lot of people weighing in on their own different perspectives.

CHAIR MALMUD: Thank you. Dr. Guiberteau.

MEMBER GUIBERTEAU: I feel exactly what was just said, that this issues have been here, and they're important issues to practicing stakeholders. And I think we've been waiting quite a while for these to be resolved, and I, personally, would not like to see anything done that would delay a final rule.

CHAIR MALMUD: Thank you. Other comments?

Dr. Langhorst.

MEMBER LANGHORST: I would, certainly, like to hear at our next meeting what is the status of the rulemaking process, and where you all are at that point in time. And that might give a balance to both sides, so that we could add some additional comments, if necessary, to hear where the NRC Staff is at that point in time.

CHAIR MALMUD: Thank you. Dr. Thomadsen.

VICE CHAIR THOMADSEN: I'm sure that we will hear where we are at that time. I don't think that that addresses, at all, the issue that's on the table, because the issue on the table is whether or not stakeholders will have the time -- the lead time necessary to make their views known at these meetings. I think that that's the issue that's on the table right now.

CHAIR MALMUD: Dr. Welsh.

MEMBER WELSH: And I would like to remind the Committee that the motion is phrased so that if the issue is resolved, we don't need to have a stakeholder meeting. If the question at hand is fully answered in the June or subsequent stakeholder meeting, this tentatively proposed reserved time at the ACMUI meeting in October may not prove to be

necessary. But I feel that it's reasonable and wise to reserve such time, if, in my opinion, the more likely event, which is we still don't have complete consensus, comes true, at least we will have ample opportunity for public notification and gathering so that we can continue this important discussion.

CHAIR MALMUD: Dr. Thomadsen.

VICE CHAIR THOMADSEN: I don't understand what you mean that the issue could be resolved. If the whole issue is trying to get input from people who feel -- from organizations that feel they don't have notice to give the input, how could that be resolved ahead, before?

MEMBER WELSH: Frankly, I don't think that it will possibly be resolved ahead of time. That's why I'm pushing forward with this particular agenda item. I don't think that we will have resolution before -- within the next few months. I'm just not optimistic that we'll have all the answers by the next meeting month.

CHAIR MALMUD: Dr. Guiberteau.

MEMBER GUIBERTEAU: I'm a little bit concerned about how we would do this, because I would feel that reading the minutes of this meeting, if we decided to save time, or reserve some time in

October, and I was a stakeholder, and I could make one of the June meetings, but it would be more convenient for me to come in October, then I might, indeed, decide that I would just wait until October, because this is likely going to be an opportunity. And if it isn't an opportunity, then we have really misled some of the stakeholders. So, I mean, I'm just concerned about how -- the logistics of this proposal.

CHAIR MALMUD: Dr. Welsh.

MEMBER WELSH: If I might reply to that, that's a very good point. However, I think all the stakeholders involved want nothing more than to see this done expeditiously, but correctly. And, therefore, those who are given adequate notice about the June meeting will be here. The stakeholder societies will have some representation. It might not be the individuals who we'd like to have there, because with such short notice, people's schedules can't be arranged. But I think everybody wants to have this done as efficiently as possible, and I don't think that we have to worry that organizations, such as ASTRO, would not have a representative at the June meeting, because we have made an announcement that there's going to be discussion in October. I

just don't think that we have to worry about that kind of an issue.

MEMBER GUIBERTEAU: But I think we need to treat all stakeholders equally. So, I mean, I don't think we can presume some stakeholders -- certain stakeholders will be sure to be here, that we would exclude -- that would include everyone. So, my feeling is that whatever we do needs to be, I think, definitive, and fair, or not at all.

CHAIR MALMUD: Thank you. Are there other comments?

MS. BHALLA: Yes. Neelam Bhalla from NRC. Dr. Malmud, also, one of the things that's being considered, or we would be waiting, NRC would be waiting for the ACMUI's final report on permanent implant brachytherapy. We have that report right now, but it's an interim report, and it seems like ACMUI asked for -- that they'll make it final report based on -- also, get the information at these public workshops. So, in our schedule going forward, we had put that report as coming up at the ACMUI fall meeting, so if we are going to extend the public workshop, or public participation going into ACMUI's fall meeting, then I guess our concern would be that that report may not be finalized, perhaps, by the end

of the year. And that report is going to be for the staff as forming the regulatory basis for the medical event definition for permanent implant brachytherapy. So, that's just one thing we would like to take into consideration.

CHAIR MALMUD: Thank you. Dr. Guiberteau.

MEMBER GUIBERTEAU: I'm somewhat unfamiliar with the process, so are we locked into June now? Is that -- do both of the meetings have to be in June?

MR. LUEHMAN: The answer to that is no. But I think as was expressed by Dr. Van Decker, and others, and I think we said it is, if we don't have the -- if we extend those pre -- they're really pre proposed rule meetings, then that's going to, potentially, delay when the proposed rule gets out, which it just extends the schedule. So, the real -- the tradeoff here is giving everybody optimal participation versus extending the schedule. I think we hear some of both here.

I mean, I think we've heard people -- members of the Committee say, including yourself, that the issues are well known. There's really no surprise on the major issues, and that we've gotten

input from many of the groups before on these issues, likely not to be anything new. And then Dr. Van Decker said, therefore, sort of why extend it? Be very careful about extending it.

So, that's going to be the tradeoff. The tradeoff is -- the answer is, if the Committee feels strongly that we haven't given the stakeholders enough time for the meetings, and you make a recommendation that you think we ought to extend it, all we're saying is that you need to take into account that by making that recommendation, if the staff goes back, considers that with management and with the Commission, that the potential outcome from that is an extension of the whole schedule. Because, unfortunately, under the APA and all the things -- the Administrative Policy Act, there are certain hoops we have to do, and there's certain amounts of time we have to give once we get into the actual rulemaking process. And once we're there, we can't save very much time there. So, there's not a lot of places we could save time.

If we move these meetings further down the road, it's likely that the rulemaking is going to move further down the road.

MEMBER GUIBERTEAU: I appreciate that

answer.

CHAIR MALMUD: Dr. Thomadsen.

VICE CHAIR THOMADSEN: Since you've already said that issues waiting until October, although to get our input, although October then would be possibly kind of late for getting stakeholder input, and ours at the same time, at least getting stakeholder input into our statement, perhaps we could find a middle ground, and have one of the meetings delayed until August. That would give time for the input to be incorporated into our statement, and into the NRC staff's planning. And that would also give at least the three months that we're requested by the professional organization to be able to plan their travel.

CHAIR MALMUD: That is a question from Dr. Thomadsen to NRC Staff. Is it possible to delay one of these workshops until August, rather than having them both in June?

MR. FULLER: Well, I guess the answer is yes, it is possible. But the impact of that is not fully known right now, because we've really looked at the other things that we have to work our schedule around through the June, early July time frame. I know there is -- there are other professional society

meetings that are later in the summer, or earlier in the fall, and I don't know exactly what those schedules are, but that would have to be looked at, and evaluated, and see what other -- there might be some other consequences that we are not aware of right now, but we could certainly look into it.

MR. LUEHMAN: I think, to follow-on with Mike, I mean, the other thing that we're trying to do, also, too, is get some -- touch on a couple of geographic locations more -- the west side of the country, and the eastern half of the country, and to -- I guess, as Mike is saying, is we could -- we'll definitely look into it, if that's the sense of the Committee, because -- but given that we want to get one in the east, one on the west, we have the additional professional society meetings, and we have some of the -- we already have other activities internal to the staff going on, we'll look at that. We don't know, as Mike said, just sitting here what all the ramifications of that would be on the schedule. But we can definitely look at that, and get back to the Committee, as to what those impacts might be to move one of the meetings a couple of months later in the year.

CHAIR MALMUD: Thank you. Dr. Welsh's

motion remains on the table. Does anyone care to call the motion?

VICE CHAIR THOMADSEN: Could you repeat the question?

CHAIR MALMUD: Would you -- it's been requested that you repeat your motion, Dr. Welsh.

MEMBER WELSH: I propose that we reserve some time at the next ACMUI meeting in the fall for stakeholder meeting purposes should such additional stakeholder meetings be necessary.

CHAIR MALMUD: Thank you for repeating the motion. All in favor of the motion?

(Show of hands.)

CHAIR MALMUD: Three in favor. Any opposed to the motion?

(Show of hands.)

CHAIR MALMUD: Seven opposed. Abstentions?

(Show of hands.)

CHAIR MALMUD: One. The motion does not carry. May I ask a question of the Committee? Would the Committee care to institute a policy that in the future when public meetings are -- when public workshops are planned, that there be a minimum number of months notice prior to the meetings in order to

satisfy the concerns of at least several organizations that would like to be represented? Dr. Welsh?

MEMBER WELSH: I fully agree with that. And part of the reason why I bring all this to the surface now is that my personal circumstances have changed, so that I need to give three months notice for any kind of time away. And this matter, which is near and dear to my heart, I will not be able to participate in, most likely, if there's a stakeholder meeting in June, because it's within the three months already. So, I agree with you, Dr. Malmud, that the three months is necessary leeway.

CHAIR MALMUD: Well, thank you. I wasn't making a statement. I was asking a question. But if that expresses your feelings, that's fine. Dr. Thomadsen, did you wish to say something?

VICE CHAIR THOMADSEN: I was going to make the motion, but I think Dr. Welsh is in the process of making the motion. Would you care to make that as a motion?

CHAIR MALMUD: Three months notice for workshops in the future, not including the current ones that are planned.

MEMBER WELSH: I would like to propose as

a motion that three months minimum lead time be provided for future stakeholder --

CHAIR MALMUD: Dr. Thomadsen has seconded. Is there any discussion of that motion? If not, all in favor of the motion?

(Show of hands.)

CHAIR MALMUD: It's unanimous. Unless there -- is there a negative? Any abstention? No, it's unanimous. So, the motion carries unanimously with regard to future workshops, not those already scheduled. I hope that is agreeable to NRC staff, and it could be worked into future plans beyond those that have already planned for and agreed upon. Thank you. And I hope that will address the concerns of the parties. I see a thumb up, which means that we have addressed the concerns of at least one professional organization in establishing that policy. Thank you.

And if we may, we'll move on to the next item on the agenda, which is Dr. Bhalla. Thank you for being so patient, Dr. Bhalla. Did I promote you? I'm sorry. It's Ms. Bhalla.

MS. BHALLA: Good morning, Dr. Malmud, Members of ACMUI, and members of the public, and, of course, the NRC staff here. I'm Neelam Bhalla, and

Ed Lohr from Rulemaking Branch. So, we are here just to give a very quick overview of the -- of what's ahead for us for this rulemaking.

Okay, a little bit of the background about Part 35 Rulemaking. Part 35 is the medical use of radioactive materials. So, as you all know, this rule, Part 35, was revised in its entirety in 2002. There were issues relating to training and experience regulations, so that part got finalized in 2005. And then in 2007 and 2009, some of the parts were revised, and those have been discussed before, so I'm not going to go into that right now.

So, where the need came for this expanded rulemaking, basically, the items were identified through implementation of Part 35. And, also, some of the issues were brought forward by the ACMUI. And, also, there was a petition for rulemaking.

In total, we have about 28 issues in this expanded rulemaking. And these potential changes have been presented in the past at various ACMUI meetings. We have as a handout available for everyone the actual list of these 28 or so items, so if you want to -- yes, it's also for the members. It's there for you in the binder.

MEMBER LANGHORST: I don't see that.

MS. HOLIDAY: Dr. Langhorst, I put them onto your desk.

(Off the record comments.)

MS. BHALLA: Sorry about that. Okay. So, you know, although you have the whole list in front of you, we have just highlighted a few items that we think may be a little bit -- need more discussions, et cetera. So, those items would be in this rulemaking is the amendment of the preceptor attestations. So, these will be related to -- well, the preceptor attestation is a very big part in the training and experience requirement for the individuals who want to be on various NRC licenses. So, there'll also be the -- again, with regard to training and experience is the Ritenour petition. And this petition was filed by AAPM.

And then one of the items would be an increase in frequency of measurement of molybdenum-99 testing. And then one of the items would be -- we put it here, Associate RSOs on a medical use license. And we think some of these items are a little bit -- they need discussions.

Going to then what about the ME rule, the Medical Event rule? Very quickly, as you all know, this rule was -- proposed rule was published in the

Federal Register August 6 of 2008. Then there were issues with that, and our working group worked on it, and there was the reproposed rule that was provided to the Commission in June of 2010. Then the Commission disapproved the publication of that reproposed rule, and that happened in August of 2010, last year.

So, what's happening with the expanded rulemaking is there is a working group that has already started to work on this rule. And the working group has members from staff from NRC, OAS and CRCPD. And we are developing the proposed rule package. And what's happening with the ME Rule is that, as you know, since morning, the workshops have been discussed. And the schedule is to have these, my slide says June 2011, but at least I get the feeling one would be happening in June, and I don't know about the others. But these workshops are very important, so far as the ME Rule is concerned. And we do plan to in the workshops, as I said, we do plan to have some of these other issues from the expanded rulemaking. And as Jim had asked the Committee before, if you do feel there are issues that we do we need to discuss, we would be happy to include those in the forthcoming workshops.

And also in your agenda, there's discussion, and Jim, and Mike had also alluded to well, there are other issues; for example, the patient release -- there'll be discussions in the -- I think it's planned for tomorrow, so there'll be discussions on that, that if there is a need to do the rulemaking. So, this is -- basically, we just wanted to give you an overview on where we are in this expanded rulemaking.

We have some supplemental slides, so if you have more questions, you can look at them. Basically, they talk a little bit more detail on the ME Rule. And, also, they have -- we have put forward just what the schedule will be going forward. So, with that, that's all we are presenting.

CHAIR MALMUD: Thank you. Are there questions or comments?

MEMBER ZANZONICO: A question.

CHAIR MALMUD: Thank you. Pat.

MEMBER ZANZONICO: Pat Zanzonico. So, the workshops are usually dedicated to specifics of these main issues, or any of the 28 items, or any of the main issues be discussed or addressed by stakeholders at any one of the workshops?

MS. BHALLA: Well, the workshops are,

basically -- you know, the Commission direction was to have the workshop on the Medical Event definition, because when we went up to the Commission, the Commission said go -- they disapproved the rule as it was proposed, and they said to go and seek out public stakeholder input on that. So, since this expanded rule is also coming up, we thought this is an efficient use of time and resources to include some of those issues also, which may come as somewhat controversial, or where folks may have some comments. And, therefore, we, perhaps, gain from those comments going forward and putting the rule package together.

MEMBER ZANZONICO: So, stakeholders would have an opportunity to bring up any issue of concern at any workshop?

MR. LUEHMAN: Yes. We will have some sessions -- again, I think we said earlier, we -- as Neelam just said, the Medical Event Rule, obviously, is going to be a main focus, because the Commission directed that. We have chosen -- we have discussed a number of the other what we'll call big ticket items that would be in Part 30, from the expanded Part 35 that we think would likely get stakeholder comments, the grandfathering provisions, and some other -- two or three other selected ones, but there will be an

opportunity at the -- whether or not there is a formal session on that piece. If there are comments that stakeholders want to provide, comments on other various parts of the 28, or submit their comments in writing, or both, they'll have that opportunity.

MEMBER ZANZONICO: So, in the formal announcement of the workshop in the Federal Register, even though it will be advertised, so to speak, as a Medical Event Rulemaking Workshop, will be specifically stated that there'll be opportunity to address other issues than Medical Events?

MR. FULLER: Yes, our plans currently are to -- in the Federal Register Notice to specify what is currently for issues that are either controversial, complex, or what we believe to be of interest to our stakeholders. However, there's no reason why we couldn't also list all of the rest of them so that people understand that those are available, if they --- we could be —- again, we're going to be in the listening mode, so if someone moves to the microphone and wants to provide us with their insights and their comments, and so forth, we will be happy to receive them.

MEMBER ZANZONICO: I'm just concerned that a potential stakeholder may not attend a

particular meeting if they're not aware in advance formally that there's an opportunity to address other -- address issues other than the one that's the advertised topic of the workshop. So, that will be included explicitly -- that opportunity will be included explicitly in the workshop announcements.

MR. FULLER: Yes.

MEMBER ZANZONICO: Okay.

CHAIR MALMUD: Thank you. Dr. Van Decker.

MEMBER VAN DECKER: A comment, and then a question. I guess, you know, now looking at your time line slides, I guess I should have read in the beginning, I guess we're talking about -- since the fact that 85 percent of the states are Agreement States, that this whole package, even if we stay to a tight time line, is not really universal until 2017. Okay.

And then my question, I guess, not per se to personally put Ms. Gilley on the spot, although she always believes I do that. In this list of 28, since we've only -- and I agree with you about the four pulled out. The UC stuff in here, the Agreement States are going to start being a little bit more concerned about because if that's the case, those are

ones we want to get highlighted up front rather than the problems we've had in the past coming to Agreement State approval at the end, and all of a sudden an 11:59 issue.

MEMBER GILLEY: I think the four that had -- Ms. Gilley. I think the four that have been identified are ones that the Agreement States are looking at. I would ask NRC if they would consider, since they do have such a major impact on the operations in the Agreement States, if there's some way to get some opportunity for relief from the compatibility requirements. If States wanted to go ahead and adopt a rule, that would address some of these issues prior to your timeline of 2014. Currently, that's not allowed, because we have to be compatible with yours, and you're actually holding up the process of Agreement States with regulations that work for medical activities by that compatibility rule.

MS. BHALLA: This -- I think the Agreement States are given three years to adopt, but there's nothing that prohibits an Agreement State to do that, to revise their regulation sooner than three years, unless there is some law against it.

MEMBER GILLEY: May I --

CHAIR MALMUD: Yes, please.

MEMBER GILLEY: Debbie Gilley. Again, yes, there is. It's compatibility with IMPEP, and it's a Compatibility B, which means we have to be identical to NRC. Our regulations have to be in content identical, so if you don't change your Medical Event or permanent implants until 2014, any state that takes the initiative to change theirs to adopt to the activity-based versus dose-based would be found incompatible with NRC.

MR. LOHR: If I may, I believe there is confusion here. I believe Neelam was saying that during the period following our final rule, they have up to three years. Her comment indicated they can adopt it during the first year if they so choose. You're absolutely right, Debbie, that before the final rule goes into the Federal Register, the states for compatibility cannot adopt them ahead of time.

MEMBER GILLEY: So, that's two and a half years that we're sitting there waiting for NRC to do regulations for us to be able to adopt them to maintain compatibility.

CHAIR MALMUD: That is correct. Thank you for bringing that to our attention. Yes, Mr. Mattmuller.

MEMBER MATTMULLER: Yes, Steve Mattmuller. Could you please explain in a little bit more detail on the direct final rule process? Because some of the next talks, they talk about it briefly, but from my perspective looking at some of these issues on this list, it seems like they'd be prime candidates for a DFR.

MS. BHALLA: To the DFR the process in itself is a fast-track process where if NRC is not anticipating any comments, then we do a proposed rule and a companion final rule, issue them out at the same time. Usually, the comment period is also lessened. It's 30 days. And then if we don't have any substantive comment, then we issue for the effective date. So, sure, it's a fast-track process, it's the shorter process, and we can do -- in this list, I'm sure there are a few items that we can do it that way. But this is -- these are then the problems that happen in rulemaking.

There is the OMB, which says we can only process one part of that Part 35 at one time. So, if we have something up the pipe, then that's it. They are only going to look at that. And then if next one comes, that's going to wait. So, there is that -- we have that risk.

And, also, it's the same, pretty much the same group that's working on this expanded rulemaking; and, therefore, if time is taken out to get a final rule, to issue some of these things, which even health and safety-wise, they don't fall into a very high priority, so if we do the -- another direct final rule, it's going to take away time from the expanded rulemaking which the group is working on.

And another thing is, for the Agreement States, then they have to go and amend their rules for those set of amendments that we would do as a direct final rule. So, these are the things which kind of go against doing another direct final rule, because it's going to just further delay the expanded rulemaking.

MEMBER MATTMULLER: If I could, a follow-up?

CHAIR MALMUD: Steve.

MEMBER MATTMULLER: When you mentioned Office of Management and Budget, when they do a review of the particular part, how long does that take?

MS. BHALLA: Generally, they have one OMB officer who's looking at and going through all of the

rules, which are, I believe, which -- from all the agencies, so it's -- we have had our rules going up there, and then we ask for extensions because this is beyond NRC staff's control. So, it could be three months, it could be four months, it could be -- so, it does -- it's -- and there is nothing we can do about it. It slows the process.

CHAIR MALMUD: Thank you. Debbie?

MEMBER GILLEY: Debbie Gilley. Is it not true that if this was an urgency from the Commissioner's level, that they could allocate resources for us to fast-track this regulation, much like they did the regulations for the 2005 Energy Policy Act?

MR. LOHR: May I? The Commission can direct the staff to take a fast-track, if you will. But because of the APA, and because of ACMUI's interactions, and because of the Agreement States' interactions on the comments that go on in the rule, very little time can be saved from what we've already proposed. We have looked at this in the Integrated Plan I believe that Steve has, and I believe you all have seen, and proposed the fastest track we feel can be actually accomplished.

There are things that we cannot change in

timeline, for example, the public comment period, or the period of time that ACMUI has to give their comments back to us, or the Agreement States' comment period back to us. So, those things add up tremendous amounts of time in the rulemaking process. I do not believe we can shave very much more off and still have a valid rule at the end.

CHAIR MALMUD: Dr. Suleiman.

MEMBER SULEIMAN: Let me give you my perspective on predicting how long it takes Office of Management and Budget to review regulations. It's unpredictable. I mean, we've had stuff from FDA, depending on how simple it is, and routine it is, go through in a couple of months, and I've -- we've had legislation -- we've had rulemaking involved with radiation safety that have taken years. And if you have a change of administration, you have a new tier of people who want to reexamine what's going up to them. And I get asked this all the time, and I've never become an accurate predictor, so I think once it clears the Nuclear Regulatory Commission, it's a whole lot more uncertain than you may think. I mean, that's just what I've shared in previous experience, it could apply here. That's why I think there's always this tendency not to -- if you can do it some

alternative way, it would be more effective.

CHAIR MALMUD: Thank you. Yes?

MEMBER SUH: Yes, I just have a general question. Do we have -- in terms of rulemaking, what's like the shortest time period for rulemaking, the longest period, and like the medium? Do we have a sense of how long it takes to have process go through rulemaking?

MS. BHALLA: Sure. In general, the -- when the Commission asks us to go ahead and do a rulemaking, in general, for the most rules, the Commission gives us one year to do a proposed rule, and then another year to do a final rule. In fact, that's our routine process. It's in our -- I think it's in the Commission processes, and our process. And then depending on the complexity of the rule, the Commission may consider giving more time, or we may ask, staff may ask more time.

And, also, if the regulatory basis is very well defined, well developed, the Commission may want to give us a little bit less time. But, in general, that's the time line there is.

MEMBER SUH: And is there a time period where it's considered too long? Like you have, let's say X number of years goes by, is it considered --

MR. LUEHMAN: Well, I think that a number of years ago, the Commission tasked the staff to, because of the length of time rulemakings were done, there was a big task force that looked at that, the length of time that it was taking rulemakings to get through. We came across with a more -- we came up with a revised process that includes the time lines, the typical time lines that Neelam is talking about, as well as a prioritization process across the Agency for all rulemakings, both -- in all the areas, so there's a common prioritization so that we can use -- make sure that we have resources where the most important rules are.

I think that we have on a typical rule pretty much achieved the time lines that Neelam is talking about, but the Medical Event Rule is an exception to that. I mean, the fact is that the staff did propose a Medical Event Rule, and the Commission denied that rule, was not happy with the rule based on stakeholder comments. So, obviously, we're back at it again, so that, obviously, didn't meet -- I mean, it went through the process, but it didn't meet the Commission's expectations, so the Medical Event Rule is going to end up taking a lot longer than the time line that's been laid out. So, I think it does

depend upon, as Neelam said the complexity and the amount of controversy or agreement there is on a particular rule.

CHAIR MALMUD: Dr. Van Decker.

MEMBER VAN DECKER: I would just make a comment now being an old man, that the last time this rule was fully opened up from the first public workshop in Philadelphia in `96 to the time everything got finalized, I think was about six and a half years. I don't think any of us want to go through that again. So, hopefully, the comments this time will be pointed and we'll move along from the community basis.

CHAIR MALMUD: Thank you for that historical perspective. Dr. Langhorst.

MEMBER LANGHORST: Neelam, before we let you go, would you go through the item numbers and tell us the four item numbers, so I can make sure I have the right ones that you mentioned.

MS. BHALLA: Okay. There is Item 9, no, sorry, not 9, Item 10 is related to grandfathering of certain certified individuals. That relates to Ritenour petition.

MEMBER LANGHORST: Yes.

MS. BHALLA: Then Item 11 is to amend

preceptor attestation requirements, and that will be across Subparts D-D and so on, because there are all these different users, and so on.

Okay. Then we have Item 15. Okay. Item 15 is about the increasing the frequency of quality breakthrough tests. 16 is actually going forward with that, not only measuring, but then with reporting requirements of the failed test. And then Item 12 is to allow -- here we said Assistant RSOs to be named on the license, but I think in my slide we said Associate RSOs. And that's -- it some work coming from what the working group is working on. And these are the things the working group also discusses. And it will be open to -- when we have -- in fact, even now, the right title we want to give the Associate RSOs, or is it the Assistant RSOs, or do we want to have something other than that.

So, I believe these are the items --

MEMBER LANGHORST: And then 28, the Medical Event, or not?

MS. BHALLA: Yes.

(Off the record comments.)

MS. BHALLA: Yes, it's somewhat related to the Medical Event, but we -- when the group started to work on Medical Event definition, this was

kind of left out for the expanded rulemaking. So, it's very similar. All 28 is saying is that right now in the regs, it's a Medical Event when a wrong radionuclide is used, but there's no provision for when a wrong brachytherapy -- isotope is used for brachytherapy. So, it's not completely going into the ME Rule, but it was pulled out to do it at this point, at the expanded rule.

MEMBER LANGHORST: Okay. So, then there's the Medical Event definition for brachytherapy, that's an additional thing.

MS. BHALLA: Right.

MEMBER LANGHORST: Okay.

MS. BHALLA: Yes, that's a qualifier. This list does not have that.

MEMBER LANGHORST: Okay.

MS. BHALLA:. It doesn't have the Medical Event definition.

MEMBER LANGHORST: And then the discussion of patient release criteria.

MR. LUEHMAN: We're going to -- that's a topic for discussion tomorrow. That's not presently in the expanded rulemaking.

MEMBER LANGHORST: Right. But that will be discussed at the workshops.

MR. LUEHMAN: The need to -- yes. Well, if you have a sense --

MEMBER LANGHORST: I'm just trying to clarify what --

MR. LUEHMAN: Right. But that's really to get a sense of the need to do rulemaking in that area, on that particular subject, rather than like what the rulemaking -- what the language would be.

CHAIR MALMUD: Mr. Fuller.

MR. FULLER: Yes, just so -- Dr. Langhorst, just so I understand your question. Your question was what things we are currently planning to discuss during the workshops in June?

MEMBER LANGHORST: That's what I was trying to --

MR. FULLER: Yes. That really, at this point in time, what we are planning to discuss are Items 10, 11, the Medical Event definition as it relates to permanent implant brachytherapy, and the need for rulemaking, and the public dose limits related to patient release, whether they should be based on a per annual basis, or on a per episode basis.

MEMBER LANGHORST: Okay. I'm sorry I did not ask that in a clear manner.

MR. FULLER: That's okay. Those are the four that we are currently planning --

MEMBER LANGHORST: Focusing on.

MR. FULLER: Planning to focus on, exactly, in those workshops.

MEMBER LANGHORST: Okay.

MR. FULLER: The others are certainly -- and any of the 28 are certainly -- when we get to the point in time in those workshops where the public can provide us with their comments and so forth, and we would be happy to entertain comments on any of those.

MEMBER LANGHORST: Thank you.

MEMBER GUIBERTEAU: Will the topic, Item 11, also include the preceptor attestation issues in 6, 8, and 24?

MS. BHALLA: They are different; 6, 8, and 24 are a little bit different, because the Item 10 is based on -- we have -- a paper was done -- no, Item 10 is -- yes, is Ritenour petition, or Item 11. Sorry. So, anyway, Item 11 has to do with -- actually, we have a Commission direction on it, and it's -- basically, what it's going to -- it's saying is that for the board-certified individuals take away the preceptor attestations, and then for the

alternate pathway, to have these attestations, the change of the wording itself. And then who can actually provide it. There is a provision that -- to be considered is that maybe radiology -- the residency directors can provide these attestations. So, this is the -- where there's the other things are more in terms of if you're going through the details of the existing regulations, then there are certain changes that need to be made, but not, necessarily, it doesn't involve all the changes in 11.

But just to give a little bit of a cautionary note here, that when we go into rulemaking, as you will see, that these are the items we start with, and then as the working group further explores that, okay, if we are making a change here within our Part 35, or whatever, which may not be so obvious on this list, or may not be on here on that list, but when we do the rule, you would see it that we may amend something, we call it the conforming changes, so that's part of the rulemaking process. But these three are separate, and not so involved as Item 11.

MEMBER GUIBERTEAU: Right. But I think if we're going to identify certain areas, it would be helpful to those in preparation for attending and

commenting on a specific area to group some of these together, so that they will know that it isn't only this one area in number 11 in terms of what we're talking about, but there are other attestation issues here. And I think that sometimes the stakeholders have pretty definite ideas about how these may be connected in a way that maybe we don't appreciate. So, my understanding is that it might be useful to do some groupings of those, so that people will know that those are all on the table, in our line of focus here in terms of amending the rule so that they'll be prepared to comment on all of them, if they wish to.

CHAIR MALMUD: Dr. Guiberteau, you are suggesting that this list be regrouped so that someone who is not familiar with these discussions could focus on specific areas, and be prepared to make comments at a public meeting. Am I correct?

MEMBER GUIBERTEAU: Yes.

CHAIR MALMUD: That's just a suggestion to regroup these, not to change them, but to regroup them for presentation.

MR. LUEHMAN: I think the staff thinks that that's fair comment. I think that the point Neelam was making is that the one that we're concentrating on -- I mean, we could do that. I

think the one that we're concentrating is the one that's going to be sort of the most changed, and there's going to be some other changes in some other areas relative to attestation, but they're not going to be as, I don't want to use the word "significant," but as extensive with changes. But we can definitely alert the stakeholders that in addition to whatever number it is, number 11, that there are other planned changes in other sections to attestation, and list those so that they're aware of those.

CHAIR MALMUD: Thank you. If we ay, we'll move on to the next item on the agenda. That's going to be a lengthy discussion, which you'll note begins before lunch, and then runs through the afternoon. It's now 11:25, and my question is, shall we break early for lunch, since we took no coffee break this morning, and begin this discussion after lunch, or are we, because of the agenda having been made public, bound to the agenda for those members of the public who might wish to participate? And, also, what are the feelings of the Committee? Dr. Welsh?

MEMBER WELSH: Well, I have a relevant question, which is do we have representation from ASTRO, who indicated ahead of time that they wished to participate?

CHAIR MALMUD: They indicated to me that via third-party that they would be here at 1:00 in the afternoon session, but might be here earlier. What's the answer?

MS. TOMLINSON: Hi, Cindy Tomlinson from ASTRO. Our representative will be here at approximately 1:00, but he was fully aware that there would be a discussion prior to the 1:00.

CHAIR MALMUD: Thank you. So, the question now goes to our own Committee. Would you prefer to break now for lunch, and then come back and start this discussion after lunch? Dr. Thomadsen?

VICE CHAIR THOMADSEN: Is the order of things that -- the first thing is you are going to be giving a background of this?

CHAIR MALMUD: Yes.

VICE CHAIR THOMADSEN: And then we go directly into public comment, et cetera? Is that the idea?

CHAIR MALMUD: As part of -- well, we will have ASTRO present here.

VICE CHAIR THOMADSEN: Well, that's at 1:00.

CHAIR MALMUD: That's at 1:00.

VICE CHAIR THOMADSEN: Yes.

CHAIR MALMUD: Yes, but we have other things to present, as well.

VICE CHAIR THOMADSEN: Okay.

CHAIR MALMUD: Would you prefer --

VICE CHAIR THOMADSEN: I would like to see, maybe we get the background presented now on schedule and then --

CHAIR MALMUD: In that case, we are --

VICE CHAIR THOMADSEN: If that timing is --

CHAIR MALMUD: In that case, Mr. Fuller, you're on.

MR. LUEHMAN: We've got about five minutes of background.

MR. FULLER: Very brief. And, in fact, if you want me to repeat this after lunch, I will be happy to do that, because it is pretty brief.

Okay. Again, in the way of introduction, the introductory slide, I'm Mike Fuller, and I'm the Team Leader for the Medical Radiation Safety Team here at the NRC.

Okay. In preparing for this presentation, I wanted to take a look at sort of the historical record behind the issue of permanent implant brachytherapy and the Medical Event

definition related to that. So, with that in mind, I looked at -- starting back -- and I imagine this may have even started before, but the -- in SECY-05-0234, the Staff recommended for all permanent implant brachytherapy that a Medical Event should be defined in terms of total source strength, and not absorbed dose.

So, then subsequent to that, in Staff Requirements Memorandum, or SRM SECY-05-0234, the Commission approved the Staff's recommendation. So, then we fast-forward to - let me get the next slide - in SECY-08-0080, the Staff provided the Commission with the proposed modified rule for the use of total activity rather than absorbed dose. And in the Staff Requirements Memorandum in response to that SECY paper, the Commission approved the proposed rule.

Okay. So, then in SECY-10-0062, the Staff provided the Commission with a reproposed rule that actually added activity-based criteria for the definition of a Medical Event for permanent implant brachytherapy, plus some requirements for training, and some other requirements. And it added the activity-based criteria to the dose-based criteria that is there. And the reason for that was that Staff recognized that as a result of the events

related to the VA Philadelphia events, or incidents, that many of the medical events that had been identified as medical events would not have been captured as medical events had we had an activity-based only medical event definition in the rule.

So, in SRM SECY-10-0062, the Commission disapproved the reproposed rule, and directed the Staff to hold a series of public stakeholder workshops. So, that's why we're here today, as we have discussed some this morning.

Now, as a way of prompting some discussion, and we've heard some of this already this morning, we wanted to provide a question that would help maybe focus some of the discussion this afternoon; and that is, how do we appropriately balance between the medical community's desire to define a medical event in terms of clinical significance with NRC's need to have mistakes in the process reported, even though there may not be an actual negative consequence to the patient?

I think Steve Mattmuller commented on that this morning in response to a comment that Dr. Welsh had made, and we hear it a lot. Now, I think that's really about all I'm going to say about that, because, again, we really want to hear from the

Committee, and members of the Committee, and members of the public who are available on their perspective on how do we make this appropriate balance between these various needs? So with that, I will conclude my opening comments.

CHAIR MALMUD: Thank you for the introduction. Are there any questions or comments for Mr. Fuller? If there are none, I would suggest that we break and regroup promptly at 1:00. Thank you, see you then.

(Whereupon, the proceedings went off the record at 11:31 a.m., and went back on the record at 1:03 p.m.)

A F T E R N O O N S E S S I O N

1:03 p.m.

CHAIR MALMUD: On the record. Ladies and gentlemen, it is 1:00 p.m. and I would ask the Committee to reassemble. We are up to Agenda Item 8 which is the Permanent Implant Brachytherapy Rulemaking. Mr. Fuller will continue the discussion on permanent implant brachytherapy.

MR. FULLER: Thank you.

Did you want to --?

MR. LUEHMAN: Yes.

Mr. Chairman, before we start on that during the lunch break we on the staff conferred on the issue of the workshops. And I don't think that we have an objection to exploring moving one of the workshops probably to the August time frame so that there's enough separation. The exact date I guess we'll pursue.

I guess the real question for the Committee would be and we're talking to the rulemaking people is they don't think that that's going to in any way affect the schedule. The one thing that it will affect though obviously is if we move one as late as August will be potentially the Subcommittee's time. It shrinks the Subcommittee's

time to give the full committee the final report on that. And if that's not an objection to the Committee that we shoot for the beginning of August and they've got approximately a little bit less than two months then to finalize the report. If that's not objectionable to them, we could move it like I said into August which would give the separation.

Really the place where the time does start impacting the schedule is after the ACMUI meeting, the next ACMUI meeting because I think that the rulemaking schedule is really predicated on getting the final Subcommittee report and being able to use that in development of the tech basis. So if that was going to be delayed, then that would start delaying the schedule. But if we move the meeting, the second meeting, to maybe the end of July/early August where we can find the right date, if that gives the Subcommittee enough time then after that second meeting to do their work, we could pursue that.

CHAIR MALMUD: Thank you, Mr. Luehman. I think we have to ask the members of the Subcommittee what their opinions are.

Dr. Welsh.

MEMBER WELSH: I can say as Chair of the

Subcommittee and the one who has done a large volume of the writing synthesizing the other Subcommittee members' opinions I think that our report can easily meet the deadline. I think that we're still waiting to hear from some input from critical stakeholders to see whether or not we've gotten it right. We believe we have. And if what we hear from ASTRO and other stakeholder organizations echoes what is written in the Subcommittee report it should be relatively quick and easy and that's what I'm anticipating.

I would like to hear from other members of the Subcommittee to see if there's any dissension.

CHAIR MALMUD: Other opinions from other members of the Subcommittee? Dr. Thomadsen.

VICE CHAIR THOMADSEN: I would second what Jim just said.

CHAIR MALMUD: And Member Langhorst agrees?

MEMBER LANGHORST: I think it can be prepared.

MR. LUEHMAN: Okay. Then we will pursue trying to move one of the meetings and still we have a -- We're probably right now just say for a target point the beginning of August sometime having one of the meetings in the June and one of the meetings in

August so that hopefully that will give enough separation. Because I mean I think the point was a good point that if you have a conflict with one week in June the next week in June you might have a similar conflict. And it also gives a little bit more notice for those stakeholders and even Committee members who have the same problems that Mr. Mattmuller enumerated about getting approval. So we'll go ahead and pursue that.

CHAIR MALMUD: Okay. Thank you.

MR. LUEHMAN: Thank you.

MR. FULLER: Well, shortly before lunch, I gave a very brief background. I gave some brief background information about at least where it seems to me where we are when it comes to the medical event definition as it relates to permanent implant brachytherapy. And I finished that up by asking or posing this question. Now there are many other questions that others may have related to this issue that would be good starting points for providing us with your insights or comments.

But I'll just put this one out there hopefully to sort of generate some discussion. And again it's how do we appropriately balance the needs of the medical community and their desires to have

the medical event in terms of clinical significant with our needs to have problems and mistakes in process identified earlier and reported to us before there is harm or less than a good outcome. So with that again I'd like to be quiet and listen and hear what you folks have to say.

CHAIR MALMUD: Thank you.

Dr. Welsh, are you prepared to lead off the discussion?

MEMBER WELSH: Thank you, Dr. Malmud.

So I would say that I and certainly all members of the Medical Events and Permanent Implant Brachytherapy Subcommittee if not all members of this Committee as a whole fully concur with your sentiments that we want to carefully analyze the definition of medical event so that it is of clinical significance and also can capture trends before they become clinically significant. It's a very fine line between those two and I appreciate that.

But one of the struggles that we have had in recent months if not years now is an assumption that in our effort to achieve this balance we are assuming that NRC is always going to decline our offers of activity- or source-strength definitions in favor of the dose-based definitions. Could you

please comment on whether or not NRC truly adheres to a dose-based definition or this is a misconception on our part that you insist on dose-based parameters?

MR. LUEHMAN: I'll start and, Mike, you can add in. I think that one thing that we -- I mean reading the regulation itself and not just the medical event definition but associated regulations when you look at the definitions in Part 35 and you look at the written directive regulation, the word "dose" in various forms whether it be prescribed dose, actual dose -- what are some other variations on dose that are -- absorbed dose are used through that definition, I mean, through those discussions.

One of the problems that we see is that I think that it's fairly clear in reading that both activity and dose can be read into the regulations as far as what is permissible to be used when delivering or when writing the written directive. But then you get into the medical event definition which then is pretty straightforward in the word in the use of dose. And the problem that we have is if you use activity then how do you assure if you deliver an activity that you have met the dose criteria for reporting. Or how is that consistently and properly converted so that you know whether you have to make a

medical event report?

MR. FULLER: If I might follow up on what Jim said, to answer your question, Dr. Welsh, at this point in time and where we are in the process and given the direction from the Commission to go out and seek input and comments from our key stakeholders and other members of the public we are very much in a posture right now of listening to whatever you think is best representing yourself, the ACMUI, the larger medical community that you are involved with.

And so I would not want to say that we are going to insist on anything. We really want to hear what you think and we are prepared to listen and accept that and to take that forward as part of our deliberations and the work that we have to do along with others.

CHAIR MALMUD: Thank you.

Dr. Suleiman.

MEMBER SULEIMAN: Okay. What I have to say is pretty straightforward. I think it's important for the medical community to know what the radiation absorbed doses they're giving to the subject, to the patient. I think to apply it at a 20 percent limit or guideline or whatever is inappropriate because different exams have different

levels of precision and accuracy.

So unless it's modality-specific or examination-specific or disease-specific, you're going to cross into that practice of medicine tolerance you know where if you're actually calculate the dose for some types of radiotherapies -- radioactive therapies -- and I'm not going to get anymore specific whether it's what organ or what type of radiation. Sometimes you may be off by 50 or 100 percent and that may well be accepted practice in the medical community. You may have other modalities where and I think we use external beam therapy where you probably have the best level of precision and accuracy out there.

So to try to characterize for all therapies 20 percent I think is problematic. And I think you may want to say depending on what it is. And I would defer to the medical community. They would know. I think the most important thing is they should know what the dose is and then they could self-regulate saying "Wait a minute. This is way outside current practice" or "This is within the normal tolerance that we'd expect in medical practice."

So I think the fundamental problem is

we're trying to make a general regulation for all medical procedures when, in fact, different medical procedures have different levels of precision and accuracy when you're talking about dose. I think that's fundamental. I don't know how you would address that within the current system.

I think the 20 percent whether it's an administered activity. To me if you know what the administered activity is and you know what the patient dimensions are you can calculate dose so they're inherently related. So that seems to be more of a calculational or technical issue.

The more fundamental question is where do you do start really restricting practice and people; it will alter their behavior just to comply with the regulations. But it could in some cases result in poor medical practice.

You may see people intentionally under-dose just so they don't get hit by the -- I take a more examination-specific approach rather than across the board 20 percent.

CHAIR MALMUD: This is Malmud. Dr. Suleiman, do you therefore feel that the limits should be set depending upon the organ which is being treated? For example, for the prostate, you have the

specific situation which would differ, of course, from other organs. Is that what you're suggesting?

MEMBER SULEIMAN: Without being any more specific, yes.

CHAIR MALMUD: That's fine.

MEMBER SULEIMAN: But you may be treating the prostate with different sources of radiation which may in turn also change that level of ability to deliver something accurately.

CHAIR MALMUD: Yes.

Does anyone else want to offer any comments about this? We have other radiation oncologists or radiation oncology physicists here?

Dr. Welsh, back to you.

MEMBER WELSH: If there are no other comments, I will add a little bit more. I don't want to sound brusque here, but I do have to say that I have an air of skepticism in part based on your previous presentation just an hour or so ago in which you stated that the SECY-05-0234 paper the medical event should be defined in terms of the total source strength, not absorbed dose. And then in the SECY-08-0080 paper the modified rule would use total activity rather than absorbed dose.

So it sounds like going back many years

the concept of absorbed dose was not favored. It seemed like activity has been promulgated. And that is what we have stated several times in the ACMUI at these meetings and in our Subcommittee reports.

Yet I know that the SECY-10-0062 reproposed rule instead of switching from dose to activity it simply added another definition which included activity which did not solve the problem in the first place, but added more complexity to the definition overall.

And so I guess it may be a rhetorical question because I know the answer. But could you explain to us why the SECY-10-0062 reproposed rule did adhere to our initial recommendations of using activity instead of dose?

MR. FULLER: Well, that does predate me a little bit. But I've done some research and had a number of conversations. So I'll give it my best shot. But if I don't get it exactly right, I'll rely upon some of my colleagues here to fill in some of the gaps.

But it is my understanding that in accordance with the recommendations from the ACMUI and direction from the Commission many years ago we were directed to write a rule that was activity-based

for permanent implant brachytherapy. Currently, we have no rule that is specific to permanent implant brachytherapy. Our rules are designed for our actual state manual brachytherapy of which permanent implant brachytherapy is a subset of that. And I guess a further subset of that would be prostates.

So we did propose a rule and it went out for public comment. And there were some -- any number of comments that it wasn't received as the perfect rule. I'm not sure exactly for what reasons or what the comments were necessarily focused on.

And then we had the incident at the VA in Philadelphia. And based upon an analysis of those medical events it was apparent to the staff at that time and maybe to others -- again I'm not sure exactly how much involvement there was on the part of the ACMUI membership -- it was at least clear to the people who did the evaluation and the analysis that many -- and I'm not sure of the exact percentage -- of those medical events would not have been reported had the medical event definition been entirely related to activity.

And so it was based upon that analysis and that understanding that the staff went back to the Commission and had a reproposed rule which you

have described. And the Commission and as a result of the paper and the meeting last July which I know a number of people from the ACMUI participated in we received the staff requirements memorandum in August which said that they had not approved that reproposed rule and for us to go back again and get it done. And get it done right is the way I received that message.

So that's why we're here today and that's why we'll be having a continuation of these discussions.

CHAIR MALMUD: DR. Thomadsen.

VICE CHAIR THOMADSEN: My understanding from the Blue Ribbon Panel report and subsequent paper from Michael Hagan that if you look at the VA events using possibly a more current version of the dose base. And I think that would be based on something like a D-90 of 80 percent instead of the entire target being plus or minus 80 percent. If you look at that and you look at a pure number-based definition pretty much you come up with the same number of events.

Have you seen both of those?

MR. FULLER: I have heard what you have described, but I have not studied that report. There

may be others here who have. But I haven't. But, yes, I have had that. That was reported to me that or to us as a staff that -- And it was presented to us in a number of different ways or described in a number of different ways.

I've heard the description you had that if we used a different dose-base criteria and went back and reevaluated. I've also heard that if you did the imaging, the post implant imaging, later and then did an evaluation of that versus activity the numbers become as far as the number of medical events much closer.

VICE CHAIR THOMADSEN: I think at the VA that would have been -- No, they didn't have that data to look at unfortunately.

MR. FULLER: Right.

MEMBER SUH: So, in terms of prostate brachytherapy, just speaking from the Department there's a lot of these. We do over 300 cases a year. And if you look at the current definition of what's you know if you look at dose-based implant our brachytherapist who does over 300 a year feels that in terms of medical event reporting there would be a portion of the cases that he has done which would be "perhaps medical events."

And there are a lot of things that a radiation oncologist when they actually do the brachytherapy they can't control. And if there's some shrinkage of the prostate depending on what method you use to localize how the prostate weight defined. So I think that putting a definite number criteria in terms of what's considered a medical event really doesn't take into account the individual differences that one may see when performing a prostate brachytherapy implant.

So I think it handcuffs the physician in terms of what he or she may be able to provide the patient, what they feel to be best. And I think one of the things that had been shown time and time again is that patients are not a number. You know, each patient has individual differences that you need to take into account.

So one of my big concerns is that prostate implant which has been shown for many years to be very effective treatment and also treatment that has few side effects that the perception out in the public may be it's not perhaps a safe treatment. And therefore some of these patients may decide to go to other treatments that perhaps may have less of a track record or perhaps more expensive as well.

So I think it's something that I think this group needs to take into account as well because you're trying to balance out what's perception versus reality. And my understanding is that I think what the proposed rules are and I think where we would like to see this, there are differences right now. But I think it's important that we take into account the individual differences that one sees when actually performing a prostate implant because it's not a cookie-cutter approach. There are going to some differences depending on what -- to help with how the prostate is done. And also each institution has individual variations as well.

In my opinion I think it is important that the NRC does not regulate the practice. I mean it's something that physicians have some control over this. They need to do what's best for the patient.

MR. FULLER: Thank you.

CHAIR MALMUD: Other comments?

(No verbal response.)

May I kind of turn this discussion around a bit and ask if you've all had a chance to read the letter from ASTRO. All members of the Committee had the opportunity to read it. They're nodding their heads. It's unanimous. Everyone has had an

opportunity to read it.

For the minutes, I would simply state that ASTRO is the professional organization, the American Society for Radiation Oncology, which governs the practice of radiation oncology professionally. And it presented to us a very concise, thoughtful and meaningful letter regarding what it regards as an optimal solution to the problem.

And that solution is expressed in the letter on pages two and three in which they discuss first of all brachytherapy clinical practice guidelines and then the definition of medical event and what they believe is an inappropriate rule for permanent implant brachytherapy. And this group represents the majority of those who practice the specialty. So we see that as an offering of a solution to the problem in their proposal.

At the same time, we recognize that we have a responsibility to the public to be concerned about situations in which ASTRO's recommendations, if they were implemented, and were not carried out according to ASTRO's recommendations could create problems for patients which need to be recognized first and addressed.

If the problem were to occur, a theoretical problem, emanating from a theoretical application of ASTRO's recommendations, there would be two means of addressing it. One would be through the medical staff regulations of each individual institute with regard to the practice of medicine, the quality of the practice of medicine. And the other would be with respect to the radiation implications which are, of course, of what's concern to us at the ACMUI and to the NRC.

In our discussions of this issue overall putting aside the ASTRO recommendation for a moment, I don't believe that there's a single solution, a single solution which would be able to capture every inappropriate treatment in advance and prevent it from occurring nor detect every less than optimal therapy and deal with it afterwards from a radiation perspective. These issues generally are detected within the quality control of the department providing the service and, of course, through the hospital or other healthcare organization's internal quality controls.

So I don't think we're going to find a foolproof solution in any of the offerings that we have, either ASTRO's or ours. However, having that

background and having read ASTRO's letter more than once, I wonder if we were to propose ASTRO's letter as a solution to the issue of prostate brachytherapy if that would create a problem for the NRC.

And that I must ask NRC staff because I have the feeling and I hope my Committee will validate my feeling that we're in favor of this, of the ASTRO recommendation. Do I read the Committee's minds correctly?

MR. FULLER: May I ask a question?

MR. LUEHMAN: No, let the Committee answer.

MR. FULLER: I'm sorry. Well, here's what I would like if you could indulge me. I noticed a lot of people going and getting it and reading it as you're speaking. And I know there is someone here from ASTRO who is prepared to actually read. Would now be a good time perhaps for all of our benefits to have that letter read and then we could continue discussing? Would that be acceptable?

CHAIR MALMUD: Yes.

MR. FULLER: I see everybody reading while you're talking.

CHAIR MALMUD: They are reading it. But they had knowledge before I made the statement that

they had read it once already.

MR. FULLER: I was talking about the people who are in the audience.

CHAIR MALMUD: Yes. The public, yes. By all means. Why don't we at this point -- I'll take your advice as sound advice.

MR. FULLER: Thank you.

CHAIR MALMUD: And ask the representative from ASTRO if that representative would introduce himself and then go through the document with us.

DR. SONG: Yes. Thank you, Dr. Malmud and Committee Members. My name is Danny Song and I thank you for the opportunity to make this statement on behalf of the American Society for Radiation Oncology. I am an Associate Professor and Clinical Director for the Department of Radiation Oncology at Johns Hopkins University. I'm also Director of Brachytherapy Services at Johns Hopkins and I have over seven years of experience in performing prostate as well as endobronchial brachytherapy. And I maintain an active brachytherapy service as well as a Federally-funded research program in prostate brachytherapy.

As you know, ASTRO is the largest radiation oncology society in the world with more

than 10,000 members. We specialize in treating patients with radiation therapies. ASTRO's highest priority has always been ensuring patients receive the safest, most effective treatments.

ASTRO, however, believes that the current definition of medical event for permanent implant brachytherapy, one that relies on absorbed dose, is particularly problematic and requires practitioners to report events that may very well fall within the range of what is considered to be medically acceptable.

I'd like to describe a little bit about permanent implant brachytherapy for those who are not familiar. It is a highly effective way of delivering radiation tailored to the shape of the tumor while sparing surrounding normal tissues.

The benefits of brachytherapy are that it is a cost effective, minimally invasive outpatient procedure that avoids hospitalization. It allows the patient a rapid recovery and rapid return to normal activity. It produces excellent ten-year outcomes with relatively low morbidity.

The high degree of accuracy achievable in prostate implants is partially due to technological improvements. But quality implants still require

skill, adequate training and attention to detail.

Permanent prostate brachytherapy is given by inserting small seeds of iodine, cesium or palladium directly into the prostate gland. The seeds are temporarily radioactive and deliver the radiation to the prostate over several weeks to months. After losing their activity, the seeds remain in the prostate and are then harmless.

It is recognized that the dose distributions following implantation are never quite exactly the same for each patient as those planned prior to the implant because the prostate gland swells and/or changes shape during and after the procedure. Because dose distributions may differ, it is important to document that actual dose that the prostate and the normal adjacent tissues will receive over the life of the implant.

This can only be determined if a post implant dosimetric assessment is performed. While the timing of such assessment may vary in part due to half-life of the particular or based on the particular isotope involved, post implant dosimetry scans are generally obtained at intervals varying from one day to one month post implant.

Under Part 35 Section 35.3045, it is

deemed to be a medical event if the total dose delivered differs from the prescribed dose by 20 percent or more. However, ASTRO believes that such a rule is not appropriate for permanent implant brachytherapy because if the NR definition is rigidly applied many medical acceptable and appropriate implants will be deemed to be medical events creating unnecessary patient apprehension.

An ASTRO working group found that the current definition of medical events was not suitable for permanent implant brachytherapy because the prostate volume enhanced the resultant calculated prostate absorbed dose depends on many factors including the timing of the imaging, the imaging modality selected, the observer variability and prostate contouring, the planning margins used. If the current dose base medical event definition remains in force many properly executed implants would be improperly classified as a medical event leading to a detrimental effect on brachytherapy practice.

Instead of a rule based on absorbed dose, ASTRO strongly recommends using an activity, i.e. source strength-based rule, where 20 percent, greater than 20 percent, or source strength implanted outside

the treatment site would define a medical event for regulatory purposes. This is because the total source strength implanted with and around the prostate is under control of the authorized user. But the subsequent prostate volume and the resulting dose of the prostate is not.

A source strength-based criterion greater than 20 percent of source strength implanted outside the planning target volume will correctly identify as medical events cases in which a large number of sources have been improperly implanted outside the treatment site but would be less likely to generate spurious medical events than a dose-based definition.

ASTRO does acknowledge one scenario where a source strength-based criterion would not adequately identify a medical event and this would be when all or most of the sources are erroneously implanted within a small region of the target volume leaving a substantial portion of the treatment site uncovered. Under this circumstance, some of the target will be overdosed and other areas would be underdosed. To address this rare event, ASTRO recommends that the authorized user be required to affirm in writing on the written directive after the implant is completed that the distribution of the

sources within the treatment site was as intended per the pre-implant written directive.

The investigation of the permanent implant brachytherapy procedures at the Philadelphia VA has brought attention to this issue and you had discussed a Blue Ribbon Panel was assembled to review the cases to determine if the implants were medically inappropriate. This panel found that many of those implants previously considered to be medical events under the current definition were in fact medically acceptable and proper. Thus, ASTRO is very concerned that if the current dose-based definition for permanent implant brachytherapy medical events remains many properly executed and medically acceptable implants will erroneously be labeled as medical events.

In the absence of reforming the definition of medical event that relies on dose-based rules, it is difficult to accurately predict how many medically acceptable implants in this country would be mislabeled as medical events. Such a situation would be harmful to the public welfare as it will create undue apprehension in patients and the general public about the safe and effective medical procedure. And it would continue to occupy the NRC,

state regulatory bodies and licensees with thousands of man hours of unnecessary and clinically irrelevant, costly investigations.

Enforcement of this rule would also lead to decreased patient access to what is well accepted as a successful and cost effective treatment which clearly would not be in the patient's best interest.

Another factor compounding the definition of medical event is the revision of medical directives. It is very important that the definition of medical event and the rules surrounding written directives take into account clinical practice realities so that certain medically acceptable implants are not labeled as medical events.

Current regulations require that revisions to the written directive be made before implantation begins. The reason the pre-implantation written directive cannot be changed is that the pre-implant written directive serves as the basis for determining if a medical event has occurred.

ASTRO would like to emphasize that many authorized users perform real-time, adaptive interactive planning whereby the written directive and the source strength to be implanted are based on the actual volume which is dynamically determined

during the procedure rather than based on the pre-implant volume. ASTRO believes that real-time planning is a more accurate method of implementation because it takes into account such alterations in the prostate volume and shape.

For those performing real-time adaptive planning implantation the total source strength to be implanted is determined interoperatively during the procedure and not pre-implant. Furthermore, even those performing brachytherapy using pre-planned techniques will often modify their plan if interoperatively they find major discrepancies in the gland or organ volume from the volumes determined during the pre-plan. Allowing flexibility to deal with real life clinical situations that become apparent during the operation improves clinical outcomes.

Accordingly, ASTRO recommends that the written directive refer to the total source strength implanted after administration but before the patient leaves the post treatment recovery area rather than an arbitrary pre-implantation written directive. We appreciate both the ACMUI's and the NRC's deliberations on this issue and look forward to working with the NRC to revise this definition so

that patients have access to safe and medically appropriate procedures.

CHAIR MALMUD: Thank you, Dr. Song. A copy of this letter will be given to the court transcriber so that it's included in the minutes having just read the letter to us.

Are there comments now with regard to the letter? Dr. Fisher?

MEMBER FISHER: Darrell Fisher. As a person who represents patient rights, I'm really quite impressed with the in-depth consideration that this letter gives the treatment of cancer in patients. And I think that that should be among our first and foremost considerations.

I know that in the slide we have in front of us we have a disclaimer even if there is no actual negative consequences to the patient. But I think what the patient really wants is an effective therapy, one that delivers sufficient radiation to the tumor or to the cancer cells present to result in an effective treatment. That's what the patient wants.

If there's a 20 percent increase to a dose to an adjacent normal tissues as a result of therapy, that's not of major concern to the patient.

The patient wants to be cured of cancer. And the patient realizes that there is going to be radiation exposure to normal tissues as a result of undergoing a patient therapy.

I think that the letter does represent my views and should be a fair representation of the rights and views of the educated patient population.

CHAIR MALMUD: Thank you, Dr. Fisher. I believe Dr. Welsh was next.

MEMBER WELSH: Thank you, Dr. Malmud. My comments are that you have probably noticed the similarity between this ASTRO letter and the ACMUI Medical Events Subcommittee, Permanent Implant Subcommittee, report even though that report is still in preliminary phases. It's virtually identical in many ways. And I believe that both documents achieved the goal of identifying trends that could lead to potential medical harm to a patient, yet are not likely to miss true medical events that are of significance. In this regard, these proposed definitions are less likely to include a large number of medically acceptable implants and mislabel them as medical events.

And as Dr. Song mentioned in this letter patient apprehension is an unwanted side effect of

identifying too many medically acceptable implants as medical events. If the term "medical event" or "misadministration" is applied too freely, it does cause patient concern and it does cause in my opinion people to steer clear of a very viable, safe and effective modality of treatment.

And as I stated in 2004 there were 41,790 prostate implants constituting about 20 percent of prostate cancer treatments. That fell to only 17,490 in 2009 falling to a very low level of eight percent of prostate treatments with the caveat that there are new competing modalities such as the robotic prostate techniques that have emerged in that time frame.

I still believe that inappropriate labeling of good implants as medical events has contributed to this decline. So it's not hypothetical in my opinion. It's real. And therefore it underscores why we need to change this definition.

This ASTRO definition and the Subcommittee's recommendation would not have labeled all of the VA series as medical events. A fair fraction of these implants would have been considered acceptable medical procedures. But I don't think that we would have missed so many either. It would

have gone under the radar and VA would not have been identified as having a problem.

So I do think that ASTRO's definition which again is similar to the Subcommittee's suggestion is quite appropriate and would identify trends that need to be identified and also not cause undue alarm that's not called for.

CHAIR MALMUD: Thank you, Dr. Welsh. Other comments? Dr. Zanzonico.

MEMBER ZANZONICO: First, I wanted to thank Dr. Song and ASTRO for their really thoughtful statement and analysis. And I don't want to speak as the Committee but it captures the sentiment of most of us.

Just kind of a logistical or practical question I have in terms of addressing the fact that the physicians properly may implant seeds sort of interactively and change on the fly appropriately in the interest of the patient, would these definitions of a misadministration -- And I'm thinking in particular not only of an inappropriate source strength implanted, but inappropriate placement, too many seeds being placed in one portion of the treatment area inappropriately. Would that require before the patient leaves the treatment area some

post treatment imaging study that's not normally or routinely performed at the present time? And, if so, should that be a component of the regulation? Otherwise it's not clear how even if the treating physician documents post treatment that they have changed or implanted seeds in what they deemed a medically appropriately way. That it was in fact accomplished if there were such an imaging study.

CHAIR MALMUD: May I address your question to Dr. Song who is a practicing radiation oncologist?

MEMBER ZANZONICO: Please.

CHAIR MALMUD: And the question is this, Dr. Song. We've heard a number of presentations in the past and I as a non-radiation oncologist recall that the tumor is first stage with imaging. Then the treatment is decided. And then there is a post treatment imaging and that has a follow-up in one or two months. Am I correct? Are there two post treatment images, one immediately following therapy and one a month or two later?

DR. SONG: I would say the most common practice is for people to obtain a scan one month after the procedure.

CHAIR MALMUD: So not immediately but

prior to and one month after.

DR. SONG: Yes. As mentioned, there is a fair amount of variability in there.

CHAIR MALMUD: Yes. And we heard that the variability includes the instrumentation used to image. Some departments are using CT. Others are using ultrasound. And that it has moved from ultrasound to CT, but not everywhere. Is that a fair summary of what is going on in the United States? I'm not speaking Johns Hopkins.

DR. SONG: Right. I would say that most centers use CT scans and it has been generally the standard for quite a while. There are some centers that are now implementing MRI because there is less of a challenge in identifying the boundaries of the prostate on MRI in the presence of seeds which do cause an effect on the CT.

CHAIR MALMUD: Dr. Zanzonico, does that answer your question?

MEMBER ZANZONICO: Well, it answers it insofar as I have a better understanding of what's currently done. But my question remains. Is that adequate in terms of capturing a medical event where a physician on the fly to use my term implants seeds in a certain arrangement.

But how do you know if the next image thereafter is one month after the fact that the seeds may have been placed properly but just because of biological processes been displaced and at one month appears to be a medical event because of what appears to be a misplacement of the seeds? Whereas, if you did an immediate post treatment image, you would either know that or not because it wouldn't be time for intervening biology, so to speak.

CHAIR MALMUD: Dr. Welsh.

MEMBER WELSH: So I'd like to just add to Dr. Song's comments. There is a lot of variability. But one procedure that is very commonly employed is use of an x-ray right after the procedure is done.

That is done for a couple of purposes. One is a simple seed count to make sure that you've done everything that you thought you'd done in terms of putting the seeds into the patient's body and figuring out if you're going to have to look around the room for a missing seed or if a seed might have traveled to the lung or elsewhere.

But I think your suggestion is sage advice and perhaps it would be very reasonable in addition to the x-ray which is typically done review the ultrasound with extra scrutiny to be able to say

after the procedure whether or not this treatment has been performed such that the distribution of sources is in accordance to the authorized users pre-implant written directive with the understanding that ultrasound is not perfect and that things change significantly interoperatively. But your suggestion is reasonable.

The practical solution would be to review the ultrasound because getting a CT scan right after implant can be challenging. And x-ray does not satisfy your question.

MEMBER ZANZONICO: It would not. A portable would not.

MEMBER WELSH: It would not satisfy the purposes of being able to say with certainty that you've placed the seeds where you intended to place them according to the directive.

CHAIR MALMUD: May I ask? I'm a little puzzled. Is ultrasound routine post therapy?

MEMBER WELSH: Ultrasound is done during the therapy.

CHAIR MALMUD: In the placement of the seeds.

MEMBER WELSH: Yes.

CHAIR MALMUD: But not a summary at the

end. Is that standard nationally? Is that standard, for example, at Hopkins?

DR. SONG: One is always looking at the ultrasound during the procedure and, as my own personal practice, yes, I do review the ultrasound to determine how the seed placement is and particularly if there are any additional areas that I need to add a seed or two. But I think ASTRO included this reference just as a theoretical possibility because one could imagine that situation.

I am challenged and they do admit with the rare event. I'm challenged to really envision a situation where that would occur where an implant is complete and yet the authorized user realizes that most of the activity was put in one part of the prostate. Because if you're using your ultrasound to determine that that's the case, then most likely one would have made a change or alteration during the procedure to keep that from happening.

CHAIR MALMUD: Our concern is what happens when the physician therapist does not do that. What happens when 20 percent of the seeds are in the bladder by mistake, not because the prostate is swollen but because they were mistakenly placed in the bladder or if they're grouped together and

there's no record of this having occurred?

DR. SONG: Well, that would be demonstrated on the post implant CT scan.

CHAIR MALMUD: And is a post implant CT scan the national standard for radiation oncology in brachytherapy?

DR. SONG: That is. Yes, that is considered a standard to be a post implant dosimetric assessment.

CHAIR MALMUD: Does that apply at the -- What I'm trying to drive at and maybe indirectly is that if our practice standards in the profession don't at the same time protect the patient from radiation damage, then there's a need for the NRC to say "Wait a minute. You don't have standards that protect the patient from these radiation accidents or misadministrations or outcomes and therefore we must at the NRC begin to look at this." Whereas we would hope that the medical practice standards would be so thorough as to prevent this.

So I guess what I'm really doing is asking you a question.

DR. SONG: Yes, there are standards.

CHAIR MALMUD: How standard -- There are standards.

DR. SONG: I know the American Brachytherapy Society which is another body and has membership consisting of people who practice brachytherapy. They do have practice standards which include a recommendation for post implant dosimetry as well as -- and Dr. Thomadsen can correct me if I'm wrong. But the American Association of Physicists in Medicine also has position papers on brachytherapy which recommend post implant dosimetry.

CHAIR MALMUD: And Dr. Thomadsen wants to make a comment.

VICE CHAIR THOMADSEN: And that is correct. In addition to saying that same thing, both standards recommend CT because at the end of a procedure ultrasound can't identify reliably all of the seeds that have been placed. As a matter of fact, there is often a large percentage that cannot be because of the orientation of the seed with respect to the ultrasound beam. So the standard is in both cases doing CT.

CHAIR MALMUD: I'll ask a naive question. Are the seeds I-131 seeds in some cases?

DR. SONG: I would say the majority of patients. Personally I used palladium most of the time. But yes.

CHAIR MALMUD: I-131.

DR. SONG: Iodine-125. I'm sorry. It's 125.

CHAIR MALMUD: And the half-life of I-125 is?

DR. SONG: Roughly 60 days.

CHAIR MALMUD: About two months.

DR. SONG: About two months, yes.

CHAIR MALMUD: So that at two months if these seeds have been placed in the wrong place the damage would have been done to the tissue other than the target organ.

DR. SONG: That's correct.

CHAIR MALMUD: And at that point what -- What we're trying to figure out is how do we prevent a recurrence of what happened at the Philadelphia VA without limiting the abilities of physicians such as yourself to practice brachytherapy. And that's a conundrum for us is protecting the patient from that unusual outcome while sustaining a very valuable therapy.

Dr. Welsh, please. You're more expert in this area.

MEMBER WELSH: Please correct me if I'm wrong. My memory is failing a bit here. But I

recall the VA -- As Dr. Song stated there are standards from the American Brachytherapy Society, from AAPM, from others, but they are not regulations. The VA had some equipment problems and post implant dosimetry was not routinely performed on many of the patients that were in this series of medical events.

Therefore, one could argue that standards were not followed, not NRC regulations mind you, but American Brachytherapy Society standards perhaps. Therefore, the NRC insists on post implant dosimetry and NRC insisted on post implant dosimetry being back to where the American Brachytherapy Society, AAPM, etc., opposed these standards I suspect that this series of medical events would have been adverted because the post implant dosimetry would have caught many of these. Before you do another one, let's reassess this program.

There is no way to prove this point. But I'm strongly suspicious I guess.

CHAIR MALMUD: Does that mean that the NRC should establish a regulation in the absence of enforcement of a practice standard by the specialty society to ensure that when something like this happens that it doesn't happen again by the same therapist? Namely, you made a mistake. We caught it

and it can't happen again because we caught it and we've now made an issue of this.

MEMBER WELSH: I would say the answer is yes. NRC perhaps should weigh in on this because it's one thing to be in violation of a society's standards. You would get a reputation to maybe not being a great doctor. Your patient volumes will suffer and you get a bad reputation.

But if you're the only doctor in town perhaps so what? If people don't listen to you, so what? But if NRC says, "This is a violation. There's going to be fine" then perhaps you're not going to practice this much longer. Or if insurance says, "You're violating the standards and you're not meeting our definition of somebody who should be practicing and getting paid for this" those are two approaches which would change physician behavior more than a society's statement which I would like to believe that everybody would adhere to. But as we see if the equipment is not working and post implant dosimetry was not absolutely mandated -- a number of patients didn't have the post implant dosimetry -- this leads to the current state of affairs.

CHAIR MALMUD: Thank you.

We have other members of the radiation

oncology profession here. Would any of you care from the perspective of either a therapist or a physicist to comment on what Dr. Welsh just said about the NRC being a regulatory body that establishing a standard of practice to do a post therapy CT when it is not enforceable? It is recommended, but not enforceable by the specialty society. I'll ask you after I ask them.

MEMBER SUH: So this is John Suh. In terms of what Dr. Welsh just mentioned, in terms of quality standards, I think if you look at what was done at the VA hospital the quality standards were probably not up to what high volume places in brachytherapy would have advised. So, as a result, some mishaps occurred.

And again with the definition that's up there saying it's a mistake that you have a deviation greater than 20 percent I think is really sending the wrong message. And whether or not the NRC can regulate a quality standard, if that's something that's within the purview of the NRC, perhaps that can drive behavior.

There's no question that for quality if you can show that your quality is not good as a result of not following standards that's one way of

changing behavior. And I think that pay for performance is perhaps one means of trying to change behavior that's less than optimal in terms of patient care.

From prostate brachytherapy, again it's a very effective therapy. It's shown to have low morbidity and I think it's important that the physicians are not so handcuffed that they will not do this procedure and not offer it.

Now in terms of talking about quality I think the other aspect of things is that I'm also a firm believer that if you're doing a procedure and you do it often you're going to be much better at it than someone who does it twice a year or three times a year. So I think along with quality standards I think the other question is, is there perhaps a certain number of cases that should be done to really be considered an expert user?

CHAIR MALMUD: I appreciate your comments, but I would make two additional comments. Number one, the VA was operating under the umbrella of one of the leading medical institutions in the United States, the University of Pennsylvania. So it was not operating without the assumption of supervision.

How that supervision worked is a long story or didn't work is another story. But that was an assumption. So this wasn't a renegade, small operation.

The other issue is that we come back to the question and that is how do we prevent what happened there at least in one case that we have seen amply covered in the news of a man who sustained considerable physical disabilities as a result. How do we prevent that from occurring and at that same time not tying the hands of radiation oncologists? And that's a struggle that we have and that we're asked to address on behalf of the public to neither constrain radiation oncology in a practice of brachytherapy and deny patients who could benefit from this generally very superior therapy and at the same time pick up incidents that occur which warn the organization that they're having a problem in their department which requires immediate reviews so that another patient doesn't have the same problem. That's the real issue.

And generally these things are handled by hospital quality control, quality assurance committees and so on. It's failed there. I don't want to accuse -- I shouldn't say it's failed. It

didn't seem to work there.

And the challenge that we have is to make sure that what happened does not occur and yet allow the therapy to thrive appropriately. And I'm trying to get advice from each of you as to how we should draft something to submit to the NRC as an advisory committee to assist the NRC and to work with ASTRO in ensuring that this important therapy continues to be provided but in a safer environment than recent history has shown has occurred.

Dr. Welsh.

MEMBER WELSH: So just to reemphasize my point. What I'm saying, strongly suggesting, is that post implant dosimetry which is an important quality assurance component of a good brachytherapy program not be recommended or strongly urged by ASTRO, ABS, Jim Welsh says you should, but should be insisted upon by NRC if it's within their purview or the insurance companies so that you don't get paid if you don't have quality programs. So I'd like comments or feedback on this very specific point.

CHAIR MALMUD: Dr. Thomadsen.

VICE CHAIR THOMADSEN: We can't deal with insurance companies. We can only deal with the NRC. No matter what criterion we use for evaluating

whether or not there has been a medical event it needs to be based in some respect on an image because you can't evaluate either for doses or where seeds are with respect to the target without that. And as such an image after the procedure seems to be necessary.

CHAIR MALMUD: Dr. Welsh.

MEMBER WELSH: I agree with what Dr. Thomadsen is saying. And I would perhaps extend it to say that irrespective of what that image shows because we haven't clearly defined what we're going to do with the post implant dosimetry today I think we are able to say that post implant dosimetry should be done as part of a program that is doing brachytherapy. If you're not doing post implant dosimetry with some form of acceptable imaging, you probably shouldn't be doing prostate brachytherapy at all.

CHAIR MALMUD: Debbie.

MEMBER GILLEY: Yes. I think that authorization may already be in NRC regulations and it's the procedures for administering requiring a written directive. And it specifically says, "Each administration is in accordance with the written directive." And I know no other way you can tell if

you didn't follow the written directive then you do some type of test afterwards to verify that you've followed that written directive. So you almost have to do some type of post dosimetry CT to validate that you followed the written directive.

CHAIR MALMUD: But almost have to doesn't mean must.

MEMBER GILLEY: I look to the experts to this table to tell me another way to validate it.

CHAIR MALMUD: A specific requirement. You wanted to say something, Dr. Suleiman.

MEMBER SULEIMAN: Well, back to imaging, I mean even in oncology, the criteria that uses response evaluation criteria for solid tumors is accurate to within 30 or 50 percent. And I think a lot of the -- I mean imaging is very, very sloppy in oncology in terms of monitoring in terms of trials over long periods of time.

So I think that imprecision and inaccuracy contributes to this issue here. When you take an image it's just not done in a standard way today. So that imprecision is factored in, in how the practice is.

But my point I'm looking at the statement. I think everybody agrees that it's

important to do a dose calculation. Now whether that's reportable to the NRC or not it's done. It's become very obvious that there has to be a post operative radiation dose calculation, a final dose estimate, whether it's activity or -- I would prefer radiation as a dose.

And when that image or when you do the dose calculation, when it's done, clearly there's a certain amount of uncertainty whether it's done immediately for seed count or whether it's done before you get an edema or whether it's a month later or six months later. That's going to vary. So you have to specify time if you're talking about change.

I think the big issue that I have problems with and I said it earlier is the 20 percent. And I would not write that in regulation. I would basically defer to -- I wouldn't say 20 percent is good or bad. I would defer to the community and say, "At what point is this difference in final radiation dose calculation bad? At what point? Is it 50 percent? Is it 100 percent?"

Years ago the debate was over how much medicine you could give somebody. I said, "Well, a gallon of penicillin people would say probably is too much." It's not a case of is there a level at which

it's not appropriate. The question is at what point do you think it's serious enough to be considered a reportable medical event? And that's where the 20 percent has to be thrown out.

And I wouldn't write it into the regulation. I would kick that into guidance. And default to the profession to define that you have to do a post operative dosimetry calculation at these following times. And if the dose calculation based on what you did initially, real time or whatever, is more than 100 percent, is more than 200 percent, is more than 500 percent, it's a reportable medical event to the NRC. But I would feel that 20 percent is too low which is why you have the controversy you have right now.

CHAIR MALMUD: Thank you.

Further comments? Dr. Thomadsen.

VICE CHAIR THOMADSEN: Ms. Holiday, could I have the slides?

MS. HOLIDAY: Yes.

(Off the record discussion.)

CHAIR MALMUD: Public comments. Would you care to introduce yourself?

MR. MOWER: I'm Dr. Herbert Mower. I'm with the American Association of Physicists in

Medicine and I'm a radiation therapy physicist.

I strongly support what ASTRO has written. In looking at -- and of course the slide just disappeared -- But it says in there even if there is no actual negative consequence to the patient.

Now I'm not a physician. But does not a psychological consequence constitute a negative consequence if you've told the patient that they have a medical event and then come back later and say it wasn't a medical event? So I feel like we kind of overlook it and we only look at what the radiation problem is.

The other question that comes up is I'm not sure when you talk about 20 percent and I would like some clarification on this. If we exceed the dose by 20 percent, where? Is this some point within the prostate? Is this some predetermined point before when we did the preplan? Because as we're all aware the closer you get to that seed you have grossly exceeded 20 percent of any dose you think you were specifically in the prostate tumor volume. Two hundred percent? Two thousand percent? You are grossly over that 20 percent number.

So if you're going to end up finding

something by 20 percent of dose, 50 percent of dose, 100 percent of dose, we have to somehow or other determine some portion of volume to which that applies. Or else it has absolutely no physical meaning.

CHAIR MALMUD: Thank you.

Dr. Welsh.

MEMBER WELSH: I do have a comment before Dr. Thomadsen begins his discussion here. This morning during our Subcommittee report on byproduct medical events, I pointed out that there was one highly unusual and slightly surprising frankly case in which 39 out of 41 seeds were within the target but were all implanted along a isoline. And this is the nightmare that we have been having for our Subcommittee in terms of coming up with an appropriate definition that is strictly activity-based.

It turns out that upon review of that particular incident it was not a medical event because the seeds were within the target volume. Yet if the D-90 is one percent, it's hard to comprehend how this would not be a medical event. Therefore, I think we have to acknowledge that there were some deficiencies with the initially proposed Medical

Event Subcommittee report, its recommendation.

The ASTRO recommendation that we've just heard now perhaps solves this problem with the statement that "the authorized user will be required to affirm in writing on the written directive after the implant is completed that the distribution of sources within the treatment site was as intended for the pre-implant written directive." So that may solve the problem.

But I think Dr. Thomadsen has another solution that I think is worthy of some discussion.

CHAIR MALMUD: Thank you.

And, with that introduction, we'll ask Dr. Thomadsen to make his presentation.

VICE CHAIR THOMADSEN: I won't take entire credit for this in that I worked with Dr. Welsh on this unless he doesn't want to have anything to do with this anymore.

(Laughter.)

And I'll preface this myself by saying I strongly endorse ASTRO's take on it. And I strongly endorse their larger report which hasn't been duplicated here but is summarized in their statement. What the intention here is to try to take the ideas behind that and address some of the practical

problems in the implementation.

Mr. Fuller, sorry to interrupt. You have the clicker. Could you advance to the next?

MR. FULLER: Be happy to.

VICE CHAIR THOMADSEN: Thank you.

Jumping right in, here's a definition of medical event. For a target, and this is strictly for prostate -- permanent prostate implant. For the target that the D-90 is less than 70 percent for the clinical target volume and simultaneously less than 5 percent of the sources occupied any octant of the PTB, except by design whereas somebody has wanted to escalate the dose or protect a region. The rationale for this is that in the RTOG-protocols, a minor deviation is the D-90 running between 90 percent and 80 percent. So obviously a D-90 of 80 percent is completely acceptable. It's not considered ideal, but it's acceptable and the patients are still allowed in protocols. So our threshold would have to be lower than that and it's quite arbitrary at 70 percent.

It's not too important where that is, because this is just a screening procedure that you find that dose on whatever post-impact imaging that one does. If that low dose is resultant from the

seed distribution being something abnormal, for example, what Dr. Welsh has pointed out where all the sources ended up in one part of the prostate, then you have a medical event. But if the distribution of the sources was within the realm of normal, and in each octant, an octant taken because it's just half in each of the three axes, a normal distribution would have 12.5 percent in each. But you shift those around and the fact that you're dealing with a template means you can't get that.

But if each octant has five percent, you have done a pretty good job of distributing the sources around and the low dose might be from the edema. It might be from some migration. It might be from a lot of possible medical conditions.

And that would not be a medical event if the sources had been distributed correctly.

But that matter, as pointed out in some of the VA nominal events that later were deemed probably not events, the distribution may not have been ideal in which case that would be a screening here, but the dose was still above what would be considered adequate for treating the prostate.

And so without failing both of those you have what would be an acceptable treatment. And for

a medical event, you would have to have a failure both in the dose distribution and in the seed distribution.

You will notice that there's no upper bound for the dose and the target as far as anybody has ever bound in the literature. There is no upper bound as far as what would be allowed for the prostate implants per dose in the target volume. As we just heard from the AAPM spokesperson, right near the source you have a singularity. The doses become extremely large anyways. So trying to have upper bound is meaningless.

Could I have the next slide, please?

The other side of a medical event is doses to normal tissue which at the moment is just point doses and some arcane holdovers from other types of exposures that the tissues might have. Looking at data as far as normal tissue responses to radiation doses that are excessive and looking for toxicity, in the bladder and the rectum, there is pretty good literature that says that the dose to the maximum dose to a 5 cc volume is what seems to be appropriate to look for normal tissue toxicity. And volumes lower than these are not predictive.

Also, looking at what data we have if we

were to use the dose to 5 cc's at the bladder or rectum that exceeded 150 percent of the prescription dose, that seems to be right in the ballpark. We could discuss and argue whether it's 150 or some other value, but that's -- I'm throwing this out as a proposal.

The other thing to worry about is the urethra. While there is no upper level on what dose we should have in the target, the urethra does have some maximum dose. Once again, it should be a volume-based dose and so the other normal tissue that we would worry about is that the dose to the urethra post-implant dosimetry not exceed 150 percent of the value that was based on the planned dose it would have otherwise gotten, because it will get some dose that's higher than the prescription dose, normally, and you just want to make sure that you aren't exceeding unduly.

And if we go back to the dose to the prostate on previous slide, the dose is something -- yes, if you could get that -- the dose would be the dose on the -- that would be prescribed just at the beginning of the implant. And this is something that's usually intended ahead of time. You look at the patient. You look at the prostate on the image

just before you do the implant. You say I have in mind that I would like to give a particular dose.

The assessment of the number of seeds is not decided ahead of time at all and we don't have a prescribed number of seeds to get that dose because in the real time implants, you don't know until you're done how many seeds you needed in order to get that dose to the target. And if you do live-time replanting in the operating room, which is the state-of-the-art at the moment, then you don't know until things are done what it is.

Can you go two slides forward, please?

So the feature of the definition is definition would catch an event where all sources were bunched. It would not signify as a medical event an impact where the sources missing an octant if you had something that was uncovered, but the dose was at least about a 70 percent of the prescribed dose.

Next slide, please.

And let's see, I already talked about that first point. So let's see, I talked about both of these here.

Next slide, please.

I think this is the last one. And having

a volume for the normal tissue tolerances -- very high variations that you get in dose that you sometimes see. If you just look for a point dose somewhere and it does have literature support as far as being a relevant quantity for the toxicity.

I think that's it. No more slides, I think. That's the proposal to try to take some of the recommendations and put them into a language that could be practically evaluated by the regulators and the practitioners. And yet, not end up with an excessive number of medical events such as some of the definitions might, nor to ignore the need from -- or the feeling from patients that their doses may be being compromised. That's it.

CHAIR MALMUD: Thank you, Dr. Thomadsen. Comments regarding Dr. Thomadsen's --

MEMBER ZANZONICO: I have two questions. First of all, this is all technically doable and routine, these quantities that are alluded to. So that doesn't hold anything special.

VICE CHAIR THOMADSEN: Yes.

MEMBER ZANZONICO: The other question I have is that the interactive seed placement that Dr. Song alluded to earlier, that's to achieve these prescribed doses at these index points. It's not to

change a dose on the fly, but to achieve a dose. Okay.

VICE CHAIR THOMADSEN: And that's what we do in our implants. We do lifetime planting.

MEMBER LANGHORST: Dr. Malmud?

CHAIR MALMUD: Yes.

MEMBER LANGHORST: Sue Langhorst. Would you then have the authorized user document these particular points and that would be what the inspector, either my staff or NRC staff or agreement staff, to then evaluate in their inspection?

VICE CHAIR THOMADSEN: By points you mean items, not physical point locations?

MEMBER LANGHORST: What I mean is the value that yes, I document that it's not less than 70 percent and not -- that you meet all the points that you're talking about, that that is documented some place?

VICE CHAIR THOMADSEN: Sure. That's pretty normal.

MEMBER LANGHORST: Right.

VICE CHAIR THOMADSEN: But the document as we explicitly at our place, when we go through our post-implant dosimetry, we have a checklist that we just check off. I assume that there would be a note

that somebody would dictate reading the image afterwards and would say looks like we've met these --

MEMBER LANGHORST: That you would have to meet these end documents for inspection purposes.

VICE CHAIR THOMADSEN: Yes.

MEMBER LANGHORST: Because that would be, I know a difficulty for my staff unless it is definitely documented some place in this format or these various criteria.

VICE CHAIR THOMADSEN: I don't know how they document now. I don't see that there would be any difference, really.

MEMBER LANGHORST: I think it just has to be clearer that these points have to be documented.

VICE CHAIR THOMADSEN: Yes, but I don't think that's a change for anybody. It's just what's being documented would be slightly different.

CHAIR MALMUD: Dr. Song?

MR. SONG: I think, of course, speaking on behalf of ASTRO, ASTRO's official position is as in the statement. I presume that this is suggested as an alternative possibility to the activity-based rule.

I think overall the spirit, and this is

me speaking personally, I think overall the spirit is reasonable. I think it does reflect clinical reality and meaningfulness. As Dr. Malmud alluded to, there are not good data about what exceeds a reasonable implant in terms of a D-90 above a certain threshold. There's just, to my knowledge, there's not good data about what that should be.

But below, yes, there's quite a bit of support for that and I think the D-90 of 70 would be a reasonable threshold to be able to achieve a good implant.

I think some of the details about the urethral dose, there may be some uncertainty there in terms of how do you see the urethra on the post-implant CT. Does that mean every patient has that Foley catheter in place?

We do a post-implant CT the day after because one of the reasons is we use a shorter half-life isotope, but also because the patients don't want another catheter put in 30 days later. And so that obviates the need for that. So there would be some challenges in doing that, but overall, I think the spirit of it seems very reasonable.

CHAIR MALMUD: Dr. Thomadsen?

VICE CHAIR THOMADSEN: Just in answer to

the urethral issue, in answer to the urethral issue, if in doing your post-implant dosimetry, there is no 5 cc volume that exceeds 150 percent of what the planned urethral dose is. You don't need a catheter in the urethra to know that the urethra is fine. And I think that that's most of the cases unless you have a congregation of sources that all happen to be right in the urethra.

I appreciate the problem and I thought about that, too. But I think in which case then you might want to do a second CT with a catheter in place, but I think the occasions where this would be the case would be extremely rare, at least looking at our implant.

CHAIR MALMUD: Dr. Welsh.

MEMBER WELSH: Jim Welsh. So our purpose as the Advisory Committee on Medical Use of Isotopes is to provide you with carefully thought out advice on medical issues. And I can assure you that for prostate brachytherapy medical event definition has been an agonizingly large amount of time, thought, and effort devoted to this.

And that's part of the reason why I might have been giving Mr. Fuller a hard time. The question which we've all had in the back of our mind

which is will NRC accept an activity-based definition such as the one from ASTRO which I personally like very much or will NRC come back and say no, we still insist on something that has dose.

We've been discussing this internally and making bets on what the Commission's decision might be.

(Laughter.)

But we thought it would be very reasonable to be prepared should we learn that our suspicion is correct when that dose-based definition is something that NRC would like to have in their definition and therefore this version has come out which I think is quite consistent with the ASTRO definition except it's got a little bit of subtle differences and includes specific parameters in terms of dose.

So our purpose has been to provide you with sound advice and I think that we have done our due diligence at this point in providing the two -- what I personally view as very acceptable definitions for medical events for prostate brachytherapy and thus our efforts to speed things along and provide you with the advice you need to make the rule, I believe has been achieved.

CHAIR MALMUD: Response? Mr. Fuller? Mr. Luehman, do you feel that the summary of this is clear or do you still feel there's some ambiguity in what we've presented?

MR. LUEHMAN: I don't think there's any ambiguity. I just would like to respond to Dr. Welsh a little bit.

I don't think that the NRC -- I think -- I haven't been involved in this since the beginning, so I can't take ownership for -- I don't really feel like I have to own necessarily what the staff has done before. I'll say I'm not a medical physicist, not a doctor, but as I have gone back and looked at how we got where we are, we as the staff, and I think that probably your perception that we're unwilling to adopt an activity-based regulation is -- I don't think it's an unwillingness.

I think what the staff has tried to do is they've tried to balance all the parts that I talked about before and quite frankly, I think Mike and I have had conversations that they're probably not -- we're probably going to have to fix more than just the definition in 30.45. We're probably going to have to look at are the definitions in the definitions section of part 35 consistent and the

wording consistent with what's in the medical directive section and consistent with 30.45. Because I think that what the staff has probably tried to do and it may come across as an unwillingness is tried to come up with a definition that sort of satisfies all the gates. And you can say that it's overly cumbersome. I won't disagree with that. I think that quite frankly in order to make this clear and unambiguous going forward, we're probably going to have look a little bit more than 30.45.

We're going to have to make sure that the wording that we carefully looked at the wording that's in -- that carries throughout Part 35, when it comes to terms that carry forward to medical events. And that includes, quite frankly, the words in the Statements of Consideration for the rule. Because if you put those with what's talked about in the Statements of Consideration for medical events, when you take that plus what's in the definition section of Part 35, the words that are in the written directive section and the words that are in the medical event definition itself, my review, this is just Jim's review and people can disagree with me. I just don't think -- I just don't think that it all hangs together really easily, that it's really easy

to understand what the intent was because I think that slightly different terminology is used in different places.

And so I don't think, Dr. Welsh, I don't think there's a resistance to it. I just think that we need to make it all work and I think that that's -- to reiterate, I think that's why we're here to listen. We're willing to go back to square one and make sure that we have a definition that I think as the Chairman said provides adequate -- that provides adequate safeguards against that case which I think that regular practitioners would say would be something that would be very surprising to them and way outside of normal medical practice. But that's kind of what we have to write -- unfortunately, sometimes, we have to write our regulations for.

I think that if you go back and look at the history of the particular events that got us to reevaluate the regulation, quite frankly, I think some of those procedures, we can argue about whether it was the 90 talked about or whether it was only 20, but it was still a fairly significant number out of a large

-- out of a relatively small overall number of cases and you know, and even the 20 percent or 25 percent

medical event, truly significant medical event population is way too much.

And so we're willing to go back and I don't think that you're going to find any unwillingness from the staff. We follow Commission direction really well and I think that our definition -- I mean our last direction from the Commission was a pretty resounding direction.

Don't you agree, Mike? What part of the no don't you understand? So I think that we're definitely open to an activity-based definition as long as like the Chairman said, we ensure that whatever definition we come up with does satisfy our need to ensure that the worst cases are captured within that definition.

CHAIR MALMUD: Dr. Guiberteau?

MEMBER GUIBERTEAU: I had another question, if you were going to comment on his --

MR. FULLER: I was just going to follow up and also to Dr. Welsh's question. I agree with Mr. Luehman. We have no -- at this point in time, there are no preconceived notions about what we will or will not entertain and -- but I do have a -- I know we're coming up on a break here in a few minutes. I have another -- as I was listening to the

presentations, I have another couple of couples that maybe we could ponder.

Number one, currently we have a rule for manual brachytherapy. We do not have a rule for permanent implant brachytherapy and at one point in time that was the direction we got from the Commission, to develop a rule and activity-based rule for permanent brachytherapy therapy. But as I listen to these discussions, we are focused entirely on prostates.

So my question is and what I'd like to hear from the Committee and others and not only today, but in future workshops or in workshops we will have in the future, do we need in your opinion a rule for permanent implant brachytherapy or do we need a rule for prostate implant, permanent implant brachytherapies, specifically for prostates?

It's just a question and I'd love what folks have to say about that.

And then my second question is that requirements for adherence with industry standards is not without precedence. And so I'd like to know how people feel about instead of having a rule that is very, very specific about plus or minus this or that percentage or what have you, if you would maybe

comment on adopting some standard or heard that there are standards and what the folks here think about having a requirement that says you must adopt some standard or we might identify that or have someone identify that for us.

Again, I'll be quiet now and listen. But I'm just interested to know the perspective.

CHAIR MALMUD: Dr. Thomadsen?

VICE CHAIR THOMADSEN: After sort of living with this question for -- since 2005 or whatever, six years, we've been addressing permanent prostate implants. I don't think we've -- we haven't really had a chance to turn our attention to other permanent implants. There aren't that many of them that most of us would have a lot of experience with. I happen to have had a bunch with other sites, but I don't think that we're in a position to say whether this would be a good rule, whatever rule we come up with for all permanent implants. I feel comfortable with saying what we've proposed is good for prostate.

To your other point, I don't think that adopting the professional standards would be particularly good because they're not like a medical event where you can say operating outside of the medical event definition is very bad. We need to

look at that. Operating outside of all of the recommendations of the professional societies are not -- is not terrible in many cases and some of the recommendations are set fairly high to try to improve the quality of performance in the field. But it's not meant to be a bar below which is considered to be of danger, is considered to be of very high quality standards. And as such, that probably does not belong in the regulation.

CHAIR MALMUD: Same subject. Dr. Welsh?

MEMBER WELSH: Well, I'll just follow up with what Dr. Thomadsen said. Well, maybe I'll start by saying that the ACMUI as a whole and perhaps especially this Permanent Implant Brachytherapy Subcommittee has been prone to thinking in terms of catastrophism, always thinking what if. So in our propositions that have been outlined in our report, we always debated internally what if they don't like it? What alternatives can we come up with?

So as I've stated before, the ASTRO recommendation that you heard today is very similar to the previous two years of implant subcommittee iterations, those previous two iterations are very similar to the ASTRO report.

But as far as your two questions, this

was and still is Permanent Implant Brachytherapy Subcommittee, but we have stated here at the ACMUI that prostate brachytherapy is so different from the other permanent implant brachytherapy procedures that we do feel that perhaps it should be as a separate category, so you could have either prostate versus non-prostate or permanent implant brachytherapy in which seeds are likely to be rearranged because of anatomy such as with brachymesh procedure or permanent implant brachytherapy in which seeds are unlikely to significantly rearrange such as prostate, perhaps breast. So that's an answer to one of your questions.

As far as the other question, without adopting standards, I appreciate what Dr. Thomadsen has said, but I might add to that by saying that it might not be unreasonable to adopt certain standards if they have been discussed with ACMUI and others and it appears that they would be reasonable to adopt. An example is what I talked about earlier, the American Brachytherapy Society and others have recommended post-implant dosimetry. I think it would be very reasonable for something of that level to be in the regulations. Perhaps aiming too high could get us into trouble. Something like insisting on

post-implant dosimetry is very reasonable and if you're not doing it, that's a medical event and maybe you need to have that called to your attention. And if you continue to not do it, then maybe you should stop doing it altogether.

So I'm halfway on that point.

CHAIR MALMUD: Thank you. There was another comment on this?

MEMBER GILLEY: I just want to bring it to your attention that adopting statements by some of the Agreement States has its own set of difficulties. It's much easier for us to adopt regulations than it is reference to a standard.

CHAIR MALMUD: Thank you. Dr. Suleiman?

MR. SULEIMAN: On the issue of adopting reference standards, we've had some good and bad experience. I think the important thing is to take what's critically important in this other standard and maybe codify it into a regulation. But when you adopt another organization's standard that may have been designed for something completely different, you run into potential problems from a regulatory enforcement point of view. But I think the post-dosimetry, that would be a very important concept to adopt.

CHAIR MALMUD: Dr. Guiberteau, did you wish to comment?

MEMBER GUIBERTEAU: Actually, Mr. Fuller asked my question, but I would like to hear from Dr. Suh on two issues, if he cares to comment. I don't want to put him on the spot. When you read 30.45 it pretty much for medical events, except for a few exceptions, applies to a broader area. And one, whether you believe that we need a more specific rule just for organ-specific rule for prostate brachytherapy. And two, if you could comment on Dr. Thomadsen's proposal?

MEMBER SUH: Sure, in reference to your first question, prostate brachytherapy, actually I would support Dr. Welsh's recommendation of the ASTRO statement where it's an activity-based definition that the authorized user confirms in writing that the seeds were placed in the intended organ; in this case it would be the prostate. And then taking minimum standards such as from the ABS, post-dosimetry is performed. So if you had those three parameters, I think it would encompass what I would like to see happen.

In terms of prostate brachytherapy, prostate brachytherapy is so much more common than

the other permanent implants that we do with radiation oncology that I would favor having prostate brachytherapy be its own entity, rather than trying to combine it with other prostate implants overall.

Your second question? This is a modification and I think it is a good starting point if the NRC feels that the ASTRO recommendations are not acceptable. It's a starting point we could go with.

These are parameters that for someone who is doing prostate brachytherapy in terms of the D-90 and what doses for bladder and rectum are received.

MEMBER GUIBERTEAU: But your first approach would be, your preferable approach would be the ASTRO approach?

MEMBER SUH: Yes.

CHAIR MALMUD: So if I may as Chair, summarize what the Committee's opinion is. The Committee feels that the ASTRO approach is the correct approach to take on behalf of patient welfare and in the sense of both protecting the patient from the radiation and protecting the patient from the anxiety which is provoked by defining a medical event as something which 10,000 practitioners and 12 members of this Committee feel is not a medical

event.

Secondly, that the post-implant dosimetry be a requirement and if it needs to be established by the NRC, we would support its establishment by the NRC in the absence of its requirement and of course, any other mechanism.

. And thirdly that prostate is a unique organ in this sense and should have a separate set of guidelines as proposed here.

Does that summarize what everyone feels?

MEMBER FISHER: Just a question. By post-implant dosimetry are you talking about activity placed or actual absorbed dose distributions?

CHAIR MALMUD: I have not defined that.

(Laughter.)

There needs to be an objective measure of some sort and I would leave that to the wisdom of the radiation oncologists and the radiation physicists to determine which measure they wish to employ. It is clear that in looking back and it's always easy to look back, the series of events, the unfortunate events that have occurred in Philadelphia would not have occurred had there been some measure employed. That's a deficiency which I think we recognize.

And beyond that, I don't think we made a

statement. We did hear comments which said that these things need to be defined a little bit better in terms of the measurement and that's not going to occur at this meeting in this session. But I think that the principles that the Committee feels are number one, to be redundant, supportive of the ASTRO recommendations; number two, requiring a means of post-implant dosimetry. It seems the current technology would require either a CT or an MRI to do that optimally. And the third issue is that prostate requires a separate set of rules.

I'll accept as a motion from Dr. Welsh --

(Laughter.)

-- if someone cares to second his motion.

MEMBER MATTMULLER: Second.

CHAIR MALMUD: And it is seconded. Any discussion, any further discussion of the motion?

MEMBER WELSH: Dr. Malmud?

CHAIR MALMUD: Dr. Welsh, this is your motion.

MEMBER WELSH: The third component of my motion, prostate versus non-prostate --

CHAIR MALMUD: Yes.

MEMBER WELSH: I again reiterate that there was some discussion within the Subcommittee

about whether instead of prostate versus non-prostate, it would perhaps be better to have implants that seek rearrangement can occur versus implants in which seed rearrangement typically doesn't occur.

Having said that, I personally would favor prostate versus non-prostate, but I know that we had this internal discussion previously and --

CHAIR MALMUD: We recognize that there will be discussions in the future regarding brachytherapy and other organs and at that time it can be decided whether or not the methodology should be standardized across the organs if it's felt to be appropriate then or not.

But I think at this point, having struggled with this issue for so long and the issue having actually become a matter of public interest in the course of these years of discussion because of what happened in my native city, but not my institution --

(Laughter.)

The -- I think we should try and capture success in this area and move on to the next one. So the motion, which has been seconded, is there any further discussion of this motion? If not, would you please all in favor say aye.

(Chorus of ayes.)

Any opposed? Any abstentions?

(No response.)

It carries unanimously and I would like to on behalf of the Committee, thank Dr. Song and ASTRO for their very thoughtful and concise and directive letter which we will hopefully submit to the NRC Commissioners and their staff with their review and consideration. Thank you.

Mr. Fuller? I turn it back to you.

MR. FULLER: Well, I am looking at the agenda and it says we're due for a break about now and then we come back from 3:30 to 5 to continue talking about permanent implant brachytherapy, but my question would be at 3:30, what do we really have left to talk about?

CHAIR MALMUD: At 3:30, I was taught by -- when I was the Vice President of the University and I would make a point at the University Cabinet and I had succeeded, I was told that anything I said from that point onward would simply take back that which I had succeeded in achieving.

(Laughter.)

And therefore silence was the rule. I would suggest that because this is a public meeting

and the public is expecting us to adhere to the program for tomorrow, that we take advantage of the opportunity to dismiss ourselves early today, rather than move the agenda ahead, if that's acceptable under the guidelines established by NRC, unless there is something more to discuss with regard to brachytherapy which is the subject on the table other than the prostate.

MEMBER LANGHORST: Sue Langhorst. Not that I'm suggesting we should go longer today, but we might avail ourselves of -- if there were any points we wanted to talk about that isn't one of these four main focus points.

CHAIR MALMUD: Is that all right under the guidelines?

MR. LUEHMAN: Yes.

CHAIR MALMUD: Then we will accept your recommendation wholeheartedly.

MEMBER LANGHORST: So we might --

CHAIR MALMUD: I see Dr. Howe has her hand up as well.

DR. HOWE: I'm wondering if the Chair would entertain maybe a discussion on what it means when a physician puts a dose because we hear that there especially in prostate brachytherapy that there

are two doses. One is 140, one is 160. But we're finding out when we look at how people are doing things, 140 means many different things. In some places you calculate a plan dose base for 140 as a D-100 when you start out. And then you evaluate.

In other places, 140 is a minimum line and the D-100 that you end up with is really much higher than that. Even the D-90 which you end up with is much higher. So it's kind of -- for us, it's very complicated to understand that not everybody has articulated things the same way. So could there be a discussion?

CHAIR MALMUD: Absolutely. We'll use the afternoon session as an opportunity to discuss both the issues raised by Dr. Langhorst and by Dr. Howe and we'll reconvene in half an hour at 3:30. Excuse me.

MEMBER GUIBERTEAU: I have another suggestion and that is if we do have the time and if Sophie agrees, would it be possible for us to discuss the dates of the proposed next meeting today rather than tomorrow as we frequently decide these dates as people are packing up and leaving and everybody has seemed to express the fact that they're very busy and

CHAIR MALMUD: That's certainly okay with

the Chair.

Sophie, is that okay? Can we handle that this afternoon?

MS. HOLIDAY: I don't see a problem with that. Actually, it will shorten the meeting for tomorrow. If that's in favor for everybody on the Committee, we can certainly do that.

CHAIR MALMUD: We'd like to do that.

MS. HOLIDAY: Certainly.

CHAIR MALMUD: So we have three items on the agenda after 3:30 and I look forward to seeing you at 3:30.

(Off the record.)

CHAIR MALMUD: It's now 3:37 and we are ready to resume our afternoon session. And the items on the agenda, if taken in order, so we can start with Dr. Howe's agenda item.

Dr. Howe would you care to just throw an item out for us to deal with --

DR. HOWE: The item is --

CHAIR MALMUD: -- other than the Japanese nuclear crisis at the moment.

DR. HOWE: The item is when we are hearing from our licensees, there are generally two numbers that are thrown out for prostate

brachytherapy, 145 and 160. And it is --

CHAIR MALMUD: I can't hear you. Speak right into it.

DR. HOWE: Okay. There are normally two numbers, 145 and 160. And so we see those numbers and we think we understand what they mean. Then we go out and we talk to licensees that we find out not everybody means the same thing. They're on different sheets of music. They're not articulating what they mean by 145 or 160.

In one case, for 145, you set that as a D-100 in your treatment planning because that's the minimum dose you want to give. In another case, it's the minimum dose they wanted to give period. And so they set something else and they deliver maybe an average of 160, 180. And they draw a line at 140 at the bottom. And they think they're giving 145 because it means something different. They're not on the same sheet of music.

And so I'd just like to have you guys address that and how we can get to the point where we understand and everybody else can understand.

CHAIR MALMUD: Thank you for raising the question. And we have volunteers to tackle it. Mr. Welsh raised his hand first.

MEMBER WELSH: So I'm going to ask my medical physicists to keep me honest here but if I recall the history behind some of this, the dose used to be 160 gray. And there was a revision of the iodine-125 dose rate constant, which was incorporated into TG-43, leading to a recalculation of the dose as 144, 145 gray, which because the dose that typically has been prescribed since then.

I don't believe that people are ignorant of this fact. So I don't think that we've seen 160 as the dose because of holdovers who have not read the TG-43 update. But what I do think is at the core of all of this is that the definition of target volume is not as clear as it could be.

We have emphasized in our committee meetings and subcommittee discussions that it would be very reasonable to standardize the terminology such that the currently used NRC language of I think it's --

PARTICIPANT: Treatment site.

MEMBER WELSH: -- treatment site was more appropriately defined as either GTV, CTV, or PTV, gross tumor volume, clinical target volume, or planning target volume respectively. And this perhaps could clarify some of your concerns in your

experiments.

DR. HOWE: So if you see a written directive that says 145 gray, what does that mean to you?

MEMBER WELSH: I would specifically then ask is that 145 to the GTV? Or 145 to the CTV or the PTV? And when that question is answered, I would have a much clearer understanding of exactly what it is supposed to be. But without that, if it's just to the treatment site, I could be dealing with any of them.

DR. HOWE: I think they use the treatment site and then the physician defines what it is based on ultrasound and gives the plan over to the medical physicist. But what we found is in some of our cases, you look at the paperwork. And if you look at the D values on the treatment plan, D-100 is 145. That was what they were trying to go for.

In other cases, they indicate they start there but then they deviate from that. And then you look at what they deliver and they are very systematic and they delivered like almost routinely 180 gray. But when you ask them what they are doing in the written directive, it's 145.

So it seems to me that they are on two

different sheets of music between the two groups.

Dr. Thomadsen?

VICE CHAIR THOMADSEN: Well, I guess there's a lot more than two groups --

DR. HOWE: Yes.

VICE CHAIR THOMADSEN: -- in that. And I think that's part of the practice of medicine. And what we've been talking about for medical events has been -- it has become quite clear -- and this is what Dr. Welsh has just been saying -- that we have to be a lot more precise in what we're calling a medical event.

And it has to be somewhat decoupled from how a given practitioner wishes to prescribe the dose because prescribing it to the minimum, prescribing it to the D-100, prescribing it to the D-90, to the D-80, all these are quite in acceptance amongst the medical community. And you wouldn't want to change that at the moment.

DR. HOWE: Well, as far as the NRC is concerned, as long as the physician has articulated what they mean, that's what it means at that practice. So we're not really talking about comparing this physician to some other practice because it is internal. That's how we stay out of

the practice of medicine. It is the physician, internal physician.

VICE CHAIR THOMADSEN: Yes.

DR. HOWE: But how do we know which sheet of music they're reading off of? Is that just always going to be a problem?

VICE CHAIR THOMADSEN: I guess that's always going to be a problem.

MR. FULLER: Mike Fuller -- may I ask a question just for my own clarification? So back to the ASTRO-recommended definitions and approach, if that is something that might perhaps ultimately be adopted, then all of these discussions and the inconsistency or the differences in the medical practice around the dose to whatever target, would be things that we really, from a regulatory perspective, would not be involved with. Is that a reasonable assumption?

VICE CHAIR THOMADSEN: Well, if I can answer, that's a really good question because part of the question would become then if the evaluation is only that you put the right -- the correct number -- the correct activity or source strength in the target, that would be correct as long as you define the target correctly. As it is right now, treatment

site is not adequate to be able to evaluate that.

MR. FULLER: If we had --

VICE CHAIR THOMADSEN: Like the dose -- using the ASTRO recommendations, all of the question that Dr. Howe was just asking and what you were saying about the dose becomes completely irrelevant, yes.

MR. FULLER: And if we had a rule where we maintained a very general term for treatment site but somehow had a requirement that the licensee had to define for themselves what the appropriate target was or the target volume and used whatever appropriate, would that also work in the construct of what ASTRO has recommended?

VICE CHAIR THOMADSEN: Sure.

CHAIR MALMUD: Dr. Welsh?

MEMBER WELSH: If I might comment, in the ASTRO proposal, the authorized user is to state explicitly the distribution of sources within the treatment site was intended per pre-implant written directive, at this point, it might be a reasonable time to also say that here is where it needs to be spelled out clearly whether or not your treatment site, which, in the written directive, it is the prescription, is talking about 145 gray to GTV, have

that spelled out, CTV, have that spelled out, or a PTV, if that is spelled out. Or if it is 160 gray to one of those.

And I think that's quite simple and easy and reasonable and should solve the dilemma that you are facing now.

CHAIR MALMUD: So, Dr. Welsh, are you suggesting that the treatment that the -- that the order for the treatment should specifically state one of those three options?

MEMBER WELSH: Yes, I personally think that it is very reasonable to state in your written directive whether you are prescribing x gray to a GTV, CTV, or PTV. And it should be easy to incorporate that into a written directive. And if necessary, to define how you have defined your CTV, PTV.

CHAIR MALMUD: Dr. Suh, do you agree?

MEMBER SUH: Yes, I think it would be wise to have the dose and what your prescription blind is going to be.

CHAIR MALMUD: And Dr. Thomadsen, you agree?

VICE CHAIR THOMADSEN: No, I don't think it's that simple. I mean it would be very nice to

have that but actually those seem completely irrelevant whatever dose you are defining in those cases because that doesn't have anything to do with defining a medical event. So the written directive doesn't need the dose specified anywhere in that.

MEMBER WELSH: If I might respond, I simply responded to Dr. Howe's question or concern in proposing a possible solution.

VICE CHAIR THOMADSEN: It seems like it is a possible solution to a problem that doesn't exist any more. If this approach were taken, you wouldn't have that.

CHAIR MALMUD: You wouldn't have the need for it?

VICE CHAIR THOMADSEN: You wouldn't have the need for that as far as the NRC is concerned.

CHAIR MALMUD: Well, what would the NRC's concern be if we -- if the NRC accepted the ASTRO proposal, what would the NRC's concern be in that case with regard to excessive or inadequate radiation to the target?

DR. HOWE: Are you directing it to me?

CHAIR MALMUD: No, to you, I'm sorry.

VICE CHAIR THOMADSEN: Oh, I thought you were addressing it to the NRC.

MEMBER MATTMULLER: No, I'm sorry, Mr. Thomadsen.

VICE CHAIR THOMADSEN: Can you ask me the question again? I thought it was addressed to them so I could sleep during that.

CHAIR MALMUD: Dr. Thomadsen?

VICE CHAIR THOMADSEN: Yes, okay.

CHAIR MALMUD: What do you think the NRC's concern would be or how could the NRC express its concern, I'll rephrase my question, how could the NRC express its concern regarding the appropriateness of the dose delivery under the ASTRO proposal?

VICE CHAIR THOMADSEN: They would not be assessing the dose delivered but that the implanted activity or source strength would be delivered. And, as I -- is that not an allowed way to write a written directive for an implant now is in source strength?

CHAIR MALMUD: Yes.

VICE CHAIR THOMADSEN: So I mean that -- you're just going back to the days before dose and just specifying how much source strength you would be implanting and they would be evaluating based on source strength.

CHAIR MALMUD: So let's say that the source strength was correct but it was in the wrong

place, now how would that be evaluated?

VICE CHAIR THOMADSEN: The radiation oncologist would specify that they put the source strength in the right location at the end of the implant. That's what it says.

CHAIR MALMUD: What if it was supposed to go into the prostate and it went into the bladder?

VICE CHAIR THOMADSEN: That isn't addressed in the ASTRO guideline. So it would be in the right location. You have to have no more than 20 percent of the seeds not in the treatment site.

CHAIR MALMUD: And what if 40 percent of the seeds went into the bladder instead of the prostate?

VICE CHAIR THOMADSEN: That would be a medical event.

CHAIR MALMUD: That's a medical event. Okay. So there's still -- we have not negated the issue of medical event.

VICE CHAIR THOMADSEN: No.

CHAIR MALMUD: We want to maintain a medical event for self-discipline if for no other reason.

VICE CHAIR THOMADSEN: Yes.

CHAIR MALMUD: Dr. -- I just wanted the

record to show that. Dr. Welsh?

MEMBER WELSH: Dr. Thomadsen brings up an important point that the ASTRO-proposed definition does introduce some subjectivity in that the authorized user, the radiation oncologist, must write in the written directive that he or she put those seeds in as intended per the written directive.

And if the seeds wound up in the bladder or the rectum or elsewhere, some might be skeptical about that authorized user's ability to make the clear statement that he or should put the seeds in the right location because it would raise the possibility that he or she is not identifying the organ as clearly as would be hoped for, for whatever reason -- lack of skill, poor imaging quality, whatever.

CHAIR MALMUD: Dr. Welsh, when you say some, is there a quantification of some having been misplaced or whatever in another organ? We know that sometimes a few will migrate. And that sometimes, from what I've heard, sometimes in placing them in the prostate since there is an attempt to get the border of the prostrate as well, if there is a concern about tumor being near the edge of the prostate, that some may get into the adjacent tissue,

whether it is rectum or bladder, is there a number beyond which you would consider it bad practice?

MEMBER WELSH: Well, we are proposing that if 20 percent are beyond what was intended, that would constitute a medical event.

CHAIR MALMUD: So we're still going to use the 20 figure? Is that correct?

MEMBER WELSH: Yes.

CHAIR MALMUD: Great. Did Dr. Thomadsen and Dr. Welsh answer your question, Dr. Howe?

DR. HOWE: I'm not sure because I really do think there's some folks out there that use the numbers in a totally different manner. Their understanding of what they're doing doesn't match up with maybe what other folks' understanding of what they are doing would be.

CHAIR MALMUD: Would it be --

DR. HOWE: And I don't think it is a volume issue. I don't think it is a question of if they use one of the three volume terminologies then you'd understand what they're doing.

In other words, I see a written directive that says 145. I see a D-100 that is for 145. And then when the actual seeds are implanted and you see the results, you see that they very consistently give

a D-90 of 180 gray.

Most of the times when you see people aiming at a D-100 in the planning stage of 140, they're going to come out under, maybe a few up. But this is consistently above that because that's what delivering 145 means to them. I don't think they're on the same sheet of music.

CHAIR MALMUD: Dr. Howe, have you ever asked them why they do that? Is it because they feel that 145 is a lower limit and they're going to give more? But they're using the number 145 as a lower limit?

DR. HOWE: That's pretty much it. They're using it as a lower limit. But when you're talking to them, you don't understand that they're talking about something totally different than what you guys at the ACMUI are talking about with 145. They really are on a different sheet of music.

And you don't know that right away. And I don't know how prevalent that it. That was -- that was where my question is coming from.

CHAIR MALMUD: Is that an issue that anyone here has come across among our radiation oncologists and physicists?

MEMBER SUH: No.

VICE CHAIR THOMADSEN: The closest I can come as an analogy is ICRU-64 recommends reporting external beam doses at the isocenter whereas lots of practitioners actually specify the dose at the periphery of whatever their target is. And a lot of them -- it's not the absolute periphery but some fraction like D-90 of the target.

Each of these practices would be giving quite different specifications for a given dose to a given target. And unless you know which on it is, you don't have a clue as to what they've actually done in the patient.

And it sounds sort of like the practices you are talking about have some inherent idea as to where they're giving the dose or how they're giving the dose that just is not getting translated to the NRC. And without going into more detail with them, it would be very hard to tell.

DR. HOWE: Thank you.

CHAIR MALMUD: Dr. Suleiman?

MEMBER SULEIMAN: Yes, I mean my observation of different professions over time is I mean as long as these authorized users are qualified, we've already established some baseline standards for the people who are using this, as long as they're

doing this dosimetry, if I might that word, in a standard way and they're doing it before and after, and they're seeing what the difference is and they're -- what difference does it make?

We've already said these are qualified people, you know? And I suspect that there are -- the people at this table and the people out in the field, and the people who never go to any of these meetings, everybody may do it differently. And as long as they meet the basic criteria, does it make any difference?

CHAIR MALMUD: Dr. Welsh, were you going to say something?

MEMBER WELSH: I do have a comment. And that is if we look at the alternative that was proposed today, eloquently stated by Dr. Thomadsen, you'll note that the proposed definition of a medical event has a lower limit, D-90 less than 70, but not an upper limit, which I think is quite relevant to what you are saying. So I want to ask Dr. Thomadsen to comment on that in relevance to what Dr. Howe has pointed out.

And number two, ask Dr. Howe if this proposed alternative definition would still face the same challenges that we brought up in the first place

here.

CHAIR MALMUD: Dr. Thomadsen?

VICE CHAIR THOMADSEN: I think it is not unusual in practice to, as one is implanting the prostate, to make sure that you get enough seeds everywhere that you cover what you want, which may result in a D-90 well over the target dose that you've originally prescribed in order to convince yourself that you've actually covered everywhere that you want adequately. And there's no evidence that that's a problem. And there's been no reported toxicity due to excessive target.

MEMBER WELSH: I would agree. I think that's standard -- common clinical practice. So I would then ask Dr. Howe if the alternative definition would face the same difficulties or would the alternative definition make your problem go away?

DR. HOWE: I think the alternative definition, as I look at it, has an underdose item number one. And that's the target.

And has an overdose in item number two because you're saying -- you're essentially saying that overdose to the cancer cells is acceptable, overdose to the urethra and the bladder and the rectum are not acceptable. And so that's how you're

defining what you would consider to be an overdose in this case. And that would probably take care of things.

I mean it's just we hear a number and we all think we understand what that number means. We think we understand from our conversations with the ACMUI what that particular site is going to be doing. And then we find out they're doing something different. The number doesn't mean the same thing to them that it does to everybody else.

But this certainly would take care of the underdose and the overdose. And I think people do -- are on pretty much the same sheet of music for underdose D-90.

CHAIR MALMUD: Thank you. If there's no further discussion of that issue -- oh, someone -- Jim, were you going to say something?

MR. LUEHMAN: Well, I was just going to say that, you know, when we actually did a -- you know went out and observed, you know, went and talked to people at the hospital to get to Dr. Howe's issue, I think that what we came to understand is that the typical practice at least there was that the doctor would say that he was looking for 145 and he was, without stating it, was really saying that that was

his D-100 so that he'd turn it over to the physicist.

The physicist, in order to get that D-100 of 145, would prescribe 165 -- you know, D-90 at 165, 170, something like that. Right, Mike? And then by doing that, they would ensure that the whole prostate or the whole target volume got at least 145.

And I think really what it came down to was that if you go back and look at the paperwork, you see the two numbers. The numbers in all cases aren't necessarily accurately described as what they were. There were just two numbers there. One was 145.

Then you go to the treatment plan. The treatment plan says 160 or 165. And you kind of scratch your head. And if you are the two people who are doing that and they've done it for a long time, they understood what those two numbers were. But just looking at the paperwork after the fact, it wasn't apparent.

It appeared that the doctor wanted 145. The physicist did something else. But, in fact, one of -- they're describing two different parameters.

CHAIR MALMUD: Are you aware of any untoward clinical effects from these --

MR. LUEHMAN: No, because again I think

that what those physicians told us is very consistent with what we've heard here, which is there's significant concern because -- for the treatment of the patient that you get, that you exceed the minimum, that you get above the minimum. But getting too much above, you know, I mean getting it too high was, again, not a concern.

I mean obviously at some really large threshold, it would be a concern. But, you know, missing it by, you know, 20 percent or whatever was not really a concern. The real concern was did you get enough to make sure that you treated the tumor or the cancer cells or whatever. So I think what we saw at the hospitals was very consistent with what has been described here.

CHAIR MALMUD: Thank you.

If we may, we'll move on to the next item on the agenda.

MEMBER MATTMULLER: Oh, I'm sorry.

CHAIR MALMUD: Excuse me, I'm sorry.

MEMBER MATTMULLER: If I could make one more comment about medical events, I think -- and I came across this statement in, as I mentioned before, in SECY-10-0062, where the NRC describes what a medical event really is, I think in regards to the

rulemaking that is slowly getting underway, that it would be important to add some of this information into the regulations as to how a medical event is defined because I think anyone who looks at it right now, if they see medical event and it meets this criteria, it is something bad. And that's not necessarily the case.

And I think the additional explanation as to what a medical event really is that is provided in the SECY is important. That ought to be included in, say, 35.2, that medical event threshold criteria is designed to detect events that have the potential to harm the involved patients. The goal of a medical event is to also detect possible problems before they arise to that level. They are then defined by the subsequent section.

And I think that is an important distinction so everyone doesn't say oh, it's a medical event. It's bad. Harm has happened. Just the potential for harm. I think that's important to include in the definition.

CHAIR MALMUD: Thank you.

I think the next item on the agenda is yours, Sue.

MEMBER LANGHORST: And I did not have any

to bring up. But I thought that might be --

CHAIR MALMUD: All right.

MEMBER LANGHORST: -- if there was anyone who wanted to bring up any of the other --

CHAIR MALMUD: That was the attachment to agenda item 5? Or 6 we're on?

MEMBER LANGHORST: I forget the number.

MS. HOLIDAY: I think it is item number six.

CHAIR MALMUD: Six? Thank you.

MEMBER LANGHORST: Yes. This is Sue Langhorst. I think many of these have been discussed in previous ACMUI meetings that an individual wanting to find more about some of this could mine that information from there. But it might be worth asking at this point when we have some extra time.

CHAIR MALMUD: Are there any questions regarding these items? There are 26 of the first side. And on the second side, I think there are just two more. Twenty-seven, 28.

Oh, yes, Dr. Van Decker?

MEMBER VAN DECKER: That way I don't have to reintroduce myself. I like that.

I guess my question is for the workshops where the rest of these are not necessarily a focus

and I can understand why. They are fairly discrete issues that have had fairly discrete ACMUI input to them. At those portions where someone might want to comment on them, I guess this sheet will be more telegraphic. You know the listing about these is here. And the solution, at least that we've talked about, is not quite clear.

So I guess, you know, on a communication basis, that those points some time will be useful to have, you know, a more expanded situation of this so that people understand where we're going.

MR. LUEHMAN: Yes, no, I think that's a good comment. I think that, you know, to the extent that, you know, we can connect that with the -- you know, where that was discussed or --

MEMBER LANGHORST: That would be great.

MR. LUEHMAN: -- the ACMUI's endorsement or comments on that particular session because as Dr. Langhorst said, the, you know, most -- many of these -- well, all of these have gone through the pipeline and are ready to go to rulemaking in some form or another already. And so we do have input on those somewhere.

And so, yes, if we do that, especially if we put that out on some kind of -- I don't know, I

think we're going to have like a website or some kind of documents that are accessible so people can read beforehand and say do I really have any comments on this issue? Or is this -- or has this, you know, part of the waterfront already been covered?

CHAIR MALMUD: Okay. That's a good suggestion. I saw another hand; I believe, earlier, did I not? Yes, sir? Steve?

MEMBER MATTMULLER: I know you would all be disappointed if I didn't talk about moly-99 at least once during this committee meeting. And this is in regards to the frequency of testing, which I'm fine with.

The only suggestion I would have for the staff in regards to this is to write this such that you state the frequency but then the actual limit is referenced to current USP standards. And rather than putting -- or keeping the current limit as it is defined now, within the regulation, and in case the limit changes in the future, as, for example, the European pharmacopeia limit is higher. And there is a harmonization process going on between the U.S. and the European pharmacopeia to where the new monograph standard for the limit might be higher.

And if that were to happen, then it would

take another rulemaking process for that to be officially recognized versus if the new reg gives the new frequency and says see USP, then we'll be covered for anything that happens in the future. And it wouldn't require another rulemaking.

CHAIR MALMUD: Dr. Howe, would you care to comment? Oh, excuse me? What would you like to comment?

MS. BHALLA: Yes, could you just go and act again? There are two things. One is how often you do the test. That is the frequency. That's what we plan to amend.

CHAIR MALMUD: Right.

MS. BHALLA: But then there is another one that you mentioned, the limit itself. And that we don't plan to do it then this time unless it's all, you know, ready being done for between the U.S. and Europe. So I just want to make that clarification that right now we were not looking at the limit, the exact, you know, moly or molybdenum per microcurie of technetium. That was not being planned to amend. Only like frequency, how often we are testing that.

MEMBER MATTMULLER: Correct. That's my understanding, too. And that's why I'm suggesting

now that not to put in the .15 microcurie per millicurie limit to put into the limit of the USP monograph.

DR. HOWE: How soon do you think that would happen?

MEMBER MATTMULLER: Well, the USP monograph process is similar to the NRC's process. Maybe a little bit quicker. But it can take several years. But I would just hate to see the Part 35 rulemaking to be approved and then the USP changes. And that could take another ten years for it to be officially employed.

CHAIR MALMUD: Sue?

MEMBER LANGHORST: Can I ask what the USP limit is right now?

MEMBER MATTMULLER: It is .15 microcuries.

MEMBER LANGHORST: So it is exactly what the NRC has now.

MEMBER MATTMULLER: What the NRC has, right.

MEMBER LANGHORST: And if the NRC puts in the rules to be at the USP limit, when the USP limit changes, then it just automatically changes for the regulations --

MEMBER MATTMULLER: Right.

MEMBER LANGHORST: -- because it is linked to that requirement.

MS. BHALLA: Yes, you know, we could put it out as one of the questions when we, you know -- because when we are regulating, it's for all, you know, all licensees from a very small say diagnostic facility to all the facilities which they may have their own pharmacists. So for a small diagnostic facility to go and find out what the US -- whatever you mentioned.

So I hate to go there and pull out the, you know, the limit. It's easier for a small licensee to just -- here is the number. And this is my limit. So that's the flip side.

MR. FULLER: If I might?

CHAIR MALMUD: Please, Mike?

MR. FULLER: As we stated earlier today, the purpose for our meeting is to listen today. And I think we've heard you. And I don't want -- you know, one of the problems is if we ask -- if we keep asking NRC staff what they think, then they're going to tell you what they think.

But really we're here to listen to you. So we did hear what you said. And we will take that

into consideration. And then, again, I appreciate that perspective and that comment. And we will certainly take that and consider it. But I don't want to have an expectation that we'll tell you what we're going to do because that's not the purpose of our meeting today.

CHAIR MALMUD: Dr. Suleiman?

MEMBER SULEIMAN: Okay, I have, again, from my own experience at FDA, introducing standards by reference has some real confusion associated with it. So the pharmacopeia may be changing it. But, you know, you could be referencing an organization that could be going in the other direction.

And so -- and then you may, if you look at the reg, you don't get an answer. And then you have to start searching for it for something else.

So my experience with writing regs is you can consider the other source, you should take that number and codify it within your regulations. But by starting to reference other documents, you start down a very slippery slope where you start -- you may -- where do you stop? So each reg should stand on its own.

I'm not arguing for or against that number. But I think using -- referencing other

standards, you've got to be careful how you do it.

CHAIR MALMUD: Does that answer your concern?

MEMBER MATTMULLER: I understand this concern but it is also my understanding that the USP limit has been always been adopted by the NRC. And -- because it used to be .15 per millicurie and then I want to say no more than 10 microcuries or nanocuries -- there was an upper limit.

And then maybe 20 years ago it was changed just to the concentration. And then the regs had to be again modified to reflect that. And so I was trying to -- my suggestion is the intent is to build a little more flexibility in the regs that if and when USP changes the limit, that when that becomes official with the USP, it becomes official NRC limits also.

CHAIR MALMUD: When we learn of it, we will move promptly. Or it may take long enough so that my successor will move promptly.

(Laughter.)

CHAIR MALMUD: Other issues for this afternoon's session? There was one other issue, I believe.

MR. LUEHMAN: The schedule.

CHAIR MALMUD: The schedule of the next meeting.

MS. HOLIDAY: Okay, if you turn to Tab 15, that will include the calendars for September and October.

MEMBER GILLEY: Sophie, did you look to see when the OAS meeting is?

MS. HOLIDAY: I did. It's actually -- OAS is in August.

MEMBER GILLEY: Okay.

MS. HOLIDAY: Okay. So as you can see, our October is pretty much taken out of the picture here. Only a limitation of the possible days. Sorry for the cut off but this is October. As you can see, it is pretty dominated by the ASTRO Annual Meeting, Columbus Day, National Radon Training Conference, and other holidays. So all that will leave us in October would pretty much be October 24th and 25th and the 27th and 28th.

So I'm proposing that we look at September, if September is okay for the Committee. Okay? So if you look for September, the Xs indicate -- are no-days because typically we don't like to start a meeting on a Wednesday. It's typically easier traveling on a Sunday and to have the meeting

on Mondays. But if you wish, we could have it starting on a Wednesday.

I spoke to Dr. Guiberteau about this earlier. I originally had the 12th and the 13th as optional days. But I understand that there is another conference going on.

MEMBER GUIBERTEAU: There is a radiology summit that week.

MS. HOLIDAY: There is a radiology summit going on the week of the 11th. So that would pretty much mark that week off for us. So my first proposal dates would be September 19th and 20th.

MEMBER SUH: There is a Gamma Knife Consortium meeting that week.

MS. HOLIDAY: Okay.

MEMBER GUIBERTEAU: A what?

MEMBER SUH: A Gamma knife Consortium meeting, the North American. It would just affect me probably.

MS. HOLIDAY: Okay.

MEMBER SUH: From the 17th to the 19th.

MS. HOLIDAY: Okay. September 17th through 19th. Okay. So would you be able to attend if we had the meeting on the 22nd and 23rd? Or would that be too close?

MEMBER SUH: If it's okay with everyone else.

MS. HOLIDAY: Okay. How does September 22nd and 23rd look for the rest of the Committee?

MEMBER ZANZONICO: It's fine with me.

MS. HOLIDAY: Okay.

CHAIR MALMUD: Does it represent a conflict for anyone? Thursday and Friday, the 22nd and 23rd?

MEMBER FISHER: I'm checking.

CHAIR MALMUD: Okay.

MEMBER FISHER: It looks clear.

CHAIR MALMUD: Dr. Fisher says it looks clear.

MEMBER WELSH: I am okay.

CHAIR MALMUD: Sue says it is okay. Anybody? A conflict for anyone here? If not, the 22nd and 23rd looks satisfactory.

MS. HOLIDAY: Okay.

CHAIR MALMUD: That's Thursday and Friday.

MS. HOLIDAY: So this will be our first choice. For a backup date, how does the 26th and the 27th of September look? I'm sorry, how does September 26th and 27th look as a backup date?

CHAIR MALMUD: A little tight.

MS. HOLIDAY: Tight? Okay. Okay. Yes?

VICE CHAIR THOMADSEN: Could I ask --

MS. HOLIDAY: Yes?

VICE CHAIR THOMADSEN: -- what is ASNC?

MEMBER VAN DECKER: American Society of Nuclear Cardiology, sir. You're welcome to come visit. We're going to have a good time at that. We'll have about 7,000 people. It's close to Louisiana.

(Laughter.)

MS. HOLIDAY: Okay. Well, if that would be tight, I propose that our backup date be October 24th or 25th.

PARTICIPANT: It sounds good.

MEMBER SULEIMAN: Oh, wait. 24th, there is an IRCP meeting in Bethesda, that International Council on Radiation Protection meeting.

MS. HOLIDAY: Okay.

MEMBER FISHER: Does that affect any of us?

MEMBER SULEIMAN: I'll probably want to go. And probably the NRC staff will want to go.

MS. HOLIDAY: Okay. Is that -- for my chain, is that that whole week? Or --

MEMBER SULEIMAN: That's just that Monday, the 24th in Bethesda.

MS. HOLIDAY: Okay. So then does October 27th and 28th pose an issue for anyone?

MS. FAIROBENT: There is an FDA meeting that day, radiological devices meeting.

CHAIR MALMUD: You need to speak into a mic. Could you speak into the mic please?

MS. FAIROBENT: Sorry, Lynne Fairobent. There is an FDA meeting that day for radiological devices advisory panel the 27th and 28th, at least on their calendar.

MS. HOLIDAY: Okay. Would that affect any of our committee members here?

CHAIR MALMUD: No, at least no one around the table that I can see. The 27th and 28th are the alternates then, right?

MS. HOLIDAY: Okay. And then, of course, if that falls through, would October 31st and November 1st pose an issue?

MR. FULLER: I will just mention that all of these dates, I think, support -- if we are able to move one of those workshops to the second week of August or somewhere in that time frame, that should support, based upon what Dr. Welsh mentioned earlier,

in other words, provide enough time for the Permanent Implant Brachytherapy Subcommittee to finalize the report for any of these dates. Would you agree with that, Dr. Welsh?

MEMBER WELSH: Yes.

MS. HOLIDAY: Okay. So for our first choice, we have September 22nd and 23rd. Our first backup date will be October 27th and 28th. And our backup backup date is October 31st and November 1st. Is that okay with the Committee?

CHAIR MALMUD: Yes.

MS. HOLIDAY: Yes? Okay.

And just to touch up on what Mike was saying about the Part 35 public workshop, it was recommended that we move our second workshop outside of June into August. So the reason that Mike suggested the second week of August is because AAPM and COMP has a combined meeting July 31st through August 4th. And there is a national conference for state legislatures on August 8th through 11th.

I'm not sure if that may affect us or not, but that's on the CRCPD's calendar. So ideally our only time to have our public workshop would be either the end of that week of August 8th or the week after that, which is August 15th through the 19th,

somewhere in there. Because as Debbie mentioned earlier, the OAS annual meeting will be August 21st through the 25th. That covers that.

CHAIR MALMUD: Okay. Any other items that we presented to the Committee this afternoon?

(No response.)

CHAIR MALMUD: Jim?

MS. HOLIDAY: Mike?

CHAIR MALMUD: Mike?

(Laughter.)

CHAIR MALMUD: I'm sorry. It's late.

MR. FULLER: No, I don't have anything else. And I pulled a fast one. No, I really don't have anything else. I certainly do appreciate all of the efforts and the discussion today. I think it has been very, very valuable to the NRC staff. And I'll look forward to another thing tomorrow of hearing your views.

CHAIR MALMUD: In that case, we will reconvene tomorrow in this room at eight o'clock for opening remarks. And then grandfathering of the Ritenour petition.

Thank you all.

(Whereupon, the above-entitled meeting was concluded at 4:29 p.m.)