Official Transcript of Proceedings

NUCLEAR REGULATORY COMMISSION

Title: Public Workshop for Discussion of Topics Related to the U.S. Nuclear Regulatory Commission's Medical Regulations

Docket Number: (n/a)

Location: New York, New York

Date: Monday, June 20, 2011

Work Order No.: NRC-950 Pages 1-236

NEAL R. GROSS AND CO., INC.
Court Reporters and Transcribers
1323 Rhode Island Avenue, N.W.
Washington, D.C. 20005

(202) 234-4433

1

UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

+ + + + +

PUBLIC WORKSHOP FOR DISCUSSION

OF TOPICS RELATED TO THE

U.S. NUCLEAR REGULATORY COMMISSION'S

MEDICAL REGULATIONS

+ + + + +

MONDAY,

JUNE 20, 2011

+ + + + +

The meeting was convened in the Midtown Ballroom of Flatotel Hotel, 135 West 52nd Street, New York City, New York, at 8:30 a.m., SUSAN SALTER, Facilitator, presiding.

PANEL MEMBERS PRESENT:

SUSAN SALTER, Facilitator

ROBERT DANSEREAU

MAUREEN EISNER

RONALD D. ENNIS, M.D.

MICHAEL HAGAN, Ph.D.

HERBERT W. MOWER, Sc.D.

JAMES S. WELSH, M.D.

RONALD ZELAC, Ph.D.

TABLE OF CONTENTS

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

(8:31 a.m.)

OPENING REMARKS/WELCOME

FACILITATOR SALTER: Well, good morning. Thank you all for coming to NRC's workshop to discuss medical regulations. My name is Susan Salter, and I am going to be your facilitator for the workshop. My role as a facilitator is really just to keep us on focus, keep us on time, get as many people to participate as we can, and everybody who wants to participate has an opportunity to do so.

Before we get started, I just want to remind everyone to turn your electronic devices on silent mode. If you need to take a call during the workshop, we certainly understand that, but we ask that you just leave the room and go out into the lobby area to do that so that you don't disturb others and everyone can continue to hear what is going on up at the front.

Restrooms are right out these doors where the refreshments were. Straight in the back, there is a men's room, ladies' room.

If you need anything during the meeting, you can let me know or go to the front desk, where the BL Seamon staff is seated. And they can answer any

questions or help you with any issues that you might have.

So, with that, I think we are ready. Are we ready to get started? All right. To get things started, I would like to introduce Cynthia Carpenter.

Ms. Carpenter is the Acting Director for the Office of Federal and State Materials and Environmental Management Programs at the Nuclear Regulatory Commission. And she is going to kick off our meeting with some opening remarks.

MS. CARPENTER: Good morning, everybody. As Susan said, my name is Cindy Carpenter. And I am the Acting Director of the Office of Federal and State Materials and Environmental Management Programs.

I want to welcome you to the NRC's stakeholder meeting on the issues associated with the medical event definition and other medical issues associated with 10 CFR part 35 that are currently being considered for rulemaking. We appreciate all of you taking the time of your very busy schedules.

This workshop is an important event for the NRC because we're able to hear your perspectives on the issues that are under consideration and these issues that are important to us as regulators but more so as the positions and the other professionals that

provide medical treatments and to the patients who receive them.

At this time, we would like to extend a special welcome to our distinguished panelists representing the Advisory Committee on the Medical Uses of Isotopes -- also we refer to them as the ACMUI -- and the agreement state partners, several professional societies that have joined us, patient right advocacy groups, NRC staff, and members of the public that are either here today or also on the webinar that we are conducting today.

The NRC considers public involvement in our activities to be a cornerstone of being a fair and strong regulator. We recognize the public's interest in the proper regulation of nuclear activities. Consequently, we provide opportunities for stakeholder participation in our program.

Consistent with the NRC's approach to open government, the agency is committed to providing meaningful opportunities for members of the public to participate in our decision-making process.

Participation also allows you to contribute your ideas and your expertise so that we can make policies and programs that benefit from this information and any of the perspectives that you share

with us today.

As you are probably aware, the mission of the NRC is to ensure the safe and secure use of radioactive materials. As an independent regulatory agency, we accomplish our mission by authorizing the use of radioactive materials through licensing. And then we oversee that through our assessment program, our inspection program, and the incident responses.

So we are here today and tomorrow specifically, the Commission directed the staff to work specifically, with the Advisory Committee on Medical Uses of Isotopes as well as the medical community to develop medical event definitions, to protect the interests of patients, and also allow physicians the flexibility to take actions that they deem that are medically necessary while preserving the NRC's ability to detect misapplication through radioactive materials.

The last ACMUI meeting that was held on April 11th and 12th was dedicated to many of the topics that are on the agenda today. And we are also going to hold a second workshop in Houston, Texas August 11th and 12th. And this will be in the center of Houston.

So over the next two days, we would really

like to hear your views and your perspectives and many of our stakeholders to discuss the definitions of medical events that are specifically related to permanent implant brachytherapy, the relaxation of preceptor attestation requirements, and extending the grandfathering to certain certified individuals.

The staff believes that it would be beneficial to the development of the proposed rulemaking language to discuss a number of these issues and other issues. And many of them are laid out in the Federal Register notice.

So the NRC staff and the Commission are very interested in your perspectives. And we want to give a thorough and thoughtful consideration to whatever we hear from you today.

Our main objective today is to listen to what you have to say, to listen and to learn as much as we possibly can learn, and take that back with us as we conduct our rulemaking. So we are looking forward to a very active participation by all of the stakeholders.

I also want to thank Dr. Malmud, who is the Chairman of the Advisory Committee on Medical Uses of Isotopes, for also taking time from his very busy schedule to be here with us. I would also like to

acknowledge all of the NRC staff. These workshops take a lot of time to put together and, in particular, Mike Fuller. You will be hearing from him today for taking the leadership role on this one.

So thank you again, all, for coming. Please actively participate. Make sure that we hear your views as we go forward with conducting the rulemaking. Thank you.

FACILITATOR SALTER: All right. Next I would like to introduce Mr. Michael Fuller. Mr. Fuller is the lead for the medical radiation safety team at the NRC in the Office of Federal and State Environmental and Management Programs.

And, with that, I'm just going to ask him to come and give us an overview of the agenda and some more opening remarks.

MR. FULLER: Thank you, Susan.

AGENDA/GROUND RULES

MR. FULLER: As Susan said, I am the team leader for the medical radiation safety team at the NRC back in Rockville, Maryland. I want to thank all of you for coming today and reiterate what Cindy said about how we recognize that you have to take time out of your busy schedules for these sorts of things. But it is very, very important to us to hear from our key

stakeholders and members of the public who are interested in this upcoming rulemaking effort. And so, again, thank you very much.

I would also like to thank our panelists. I see Dr. Welsh got here. If you want to at any time come on up. We've got a space for you here on the first panel.

But I want to thank all of the panelists for taking time out to be with us today. I especially want to thank Bob Dansereau from the State of New York. He stepped up. And we had a different person. Cheryl Rogers from Wisconsin was supposed to be here. And in the 11th hour, she was unable to make it. So, Bob, thank you very much for stepping in at the last minute for Cheryl.

I want to reiterate something that Cindy said. You know, we're pretty early in the rulemaking process here from the medical event definition as it relates to permanent implant brachytherapy and some of the other things that we'll be talking about over the next couple of days.

We as NRC staff members are here. And the main objective of this workshop is for us to listen and to hear what you have to say about what we should do or not to do, but we're here to listen and to learn

primarily.

So we're not here this week to provide solutions to problems or recommended approaches for rulemaking or recommended rules. That will come down the road as we get closer to development of proposed rules. We are here to listen to what you, our key stakeholders and interested members of the public want to tell us about what we need to understand.

I will go over the agenda here for just a couple of moments. Today's activities are focused and devoted, I should say, entirely to the medical event definition as it relates to primary implant brachytherapy and other issues related to that.

And, in fact, the reason we are having these workshops is because we were directed by the Commission last fall, late last summer, early last fall, to hold these workshops to seek public input and to work with our key stakeholders and the broader medical community as well as the ACMUI.

And we have added day two with some of the other rulemaking activities that are ongoing again in the early stages, what we have been referring to in the last several months as the expanded part 35 rulemaking. There are a number of issues that are currently in that process.

Today we are going to talk about the medical event definitions. This morning we are going to have some series of presentations from the panelists that you see sitting up here. After that, we will take a quick break and come back. And then there will be a panel discussion amongst the panelists.

And that hopefully will carry us on up until lunchtime or so. I don't think that there will be any lack of interest amongst the panelists of having a very fruitful discussion, and we're looking forward to that.

After lunch and for the remainder of the day, we will have opportunities for those of you in the audience, members of the public, and through the webinar folks that are participating that way to provide us with your comments, your suggestions, your recommendations, and so forth.

I'm going to ask the panelists to sort of stay up here in the afternoon so that if anyone wants to ask for clarification on something that they heard this morning, then they are available to address those sorts of things. So that will be today. That should carry us on up into late this afternoon.

Tomorrow morning we'll start again at

8:30. And we will have a number of topics. We will have another panel discussion to talk about the relaxation of preceptor attestation requirements and extending grandfathering to certain certified individuals. This is commonly referred to as the Ritenour Petition. That will go in the morning.

And, again, it will be a few presentations and then a panel discussion. And then we'll open that up for public comments as well. And that will be for the first hour and a half or so in the morning.

And then after a break, we will have a series of presentations. NRC staff person will provide a status and background information, some things that are currently being considered for rulemaking.

And then there will be opportunities for public comment and suggestions and recommendations and so forth on each of these. They have to do with naming associate or assistant radiation safety officers and also some additional molybdenum breakthrough testing and reporting requirements.

Then late in the day tomorrow, late in the afternoon, we have a number of other issues and items that are under consideration for rulemaking. And a lot of these are administrative in nature and fairly

straightforward. So we will open it up for public comment on that late tomorrow afternoon.

So that is a little bit of a rundown on how the two days will go. Susan will keep us straight -- I am confident of that throughout the process -- as our facilitator. And everyone should have a copy of the agenda in your package. So we will just sort of follow along.

So, again -- oh, one other thing I wanted to mention, everyone has a blue card. And there are others available. When we get to the public comment period this afternoon, what we would like for you to do is to fill out a blue card if you want to make a comment or recommendation or what have you. We will have some microphones set up here at the front of the tables for that after lunch.

It also has a place on here to write out your comment. Now, if you're going to come to the microphone to make a comment, you don't have to write out your comment. That is only for someone who if you -- for whatever reason, you want to make a comment or you want to maybe ask for clarification or something. Then you could actually write that out, and somebody could read it for you or if you just wanted to make some notes to yourself.

But what we need these blue cards for is we are transcribing this meeting. And so it is very important that everyone who speaks speaks into a microphone and also provides us with your name and who you are affiliated with, if any.

And if you will fill out these cards and then hold them up, myself or one of the other members of the staff here at NRC will come by and collect those and get those to Susan. And Susan will have the names of the people to call to the microphones. It makes for a very orderly process, we don't have a lot of people lined up in the aisles waiting to get to the microphone. Susan can say like "Okay. We have Dr." so and so, "who is going to provide us with his remarks. And then after that, we'll have Ms." so and so "and then after that." So you will know sort of where you are in the line.

We also have yellow cards. These are only for the purposes of being added to our mailing list. As we move farther down the road in this process for rulemaking, there will be opportunities for folks to participate in various ways in order to keep everyone informed of where we are in the process.

We have a medical list server that we send e-mails out. So if you fill out a yellow card, if

you're not already on the NRC's medical list server, if you fill out a yellow card, we will make sure you get added to that. And then you will be aware of where we are in the process.

So that's about all I had. Susan? Thank you.

FACILITATOR SALTER: Something else on the blue cards, if you could hand them in to the front desk during breaks or at lunchtime, that would be great. That way we won't come and lose them. But you can fill out a blue card any time throughout the day. So even if right now you don't want to make a comment but you hear a comment that you would like to respond to, you can fill out a blue card at that time, and you can give it to one of the NRC folks in the room. Until that time, if you could drop them off at the front desk, that will help us from losing them.

Also, if you want to make a comment and you also want to be on the mailing list, you can do both of those things on the blue card. Yellow card is only if you're not making a comment and you want to get on the mailing list.

Finally, for blue cards, only fill out a blue card today if you want to speak today. If you are going to speak tomorrow, we will ask you to fill

out a blue card tomorrow so that we don't get confused about what day folks want to talk. So that is kind of the blue card.

I would like to take a minute to introduce Gretchen Rivera-Capella sitting over at the round table. She is manning our webinar. For folks on the webinar, you should also if you're hearing me be on a bridge line on the telephone. And while you can hear what is going on in this room, we cannot hear you. So when we get to the public comment portion of the workshop this afternoon, you will type your question into the webinar. And Gretchen will read that comment for the group.

If you have trouble, some technical difficulties while you are on the webinar, you can also type that in and Gretchen can help, try to help resolve that or get someone who can resolve that.

So that's our webinar. That's the comment portion. Before we get started with the panel presentations, just a couple of things that we can all do to make the meeting run smoothly. As Mike indicated, we are having the meeting transcribed. So we ask that you refrain from like sidebar conversations or conversations at your table because all of that stuff will be picked up. It will be

difficult to get an accurate copy of the meeting.

So please remember to do that. If you need to have a conversation, just step outside. That's fine. We certainly understand that.

As Mike said, the beginning, the morning portion of our meeting is panel presentation and discussion. And that's really just the time for you to hear from the panel. We won't be going to the audience for any comment. During that time, we ask that you don't shout out because, again, we're trying to get a good copy of the meeting. And the transcriber won't know who you are and won't be able to get that comment. So please hold that until this afternoon.

Let's see. The other thing that I just wanted to remind everyone about, probably don't need to, but I am going to anyway, is we have a lot of different positions and ideas in this room. And you're going to hear some that you agree with, and you are going to hear some that you don't agree with. But we need to keep our passions in check and make sure that we show nothing but respect for the individuals in their positions during the next two days. And hopefully that will really get some good dialogue going.

So if there is nothing else, I think we have covered everything. I think what I am going to do, you have bios in your packet for all of our panelists. We have a very distinguished group of panelists, who have a breadth of knowledge on these topics.

So, rather than me read all of those bios because you can do that, we also have them posted on the website -- I am just going to briefly introduce them as they make their way up to the podium. Your presentations are on the laptop. Just hit "ESCAPE." There's a folder. You can pull it up. All the presentations are in order. If you need some help, Mike can come up and help you.

So our first speaker is going to be Dr. Ronald Zelac, who is a radiological health and safety specialist, who has been active in educational research in applied areas of the field. He is currently employed as a senior health physicist at the Nuclear Regulatory Commission. And he presently focuses on the medical use of radioactive materials, including regulations, guidance, and implementation issues.

Dr. Zelac is certified by the American Board of Health Physics and the American Board of

Medical Physics. And he is going to start our panel presentation off with some background information on the topic.

DR. ZELAC: Thank you, Susan. Everyone can hear me, I hope? Good.

TOPIC 1: MEDICAL EVENT DEFINITION ASSOCIATED WITH BRACHYTHERAPY

- PANEL PRESENTATIONS

As you just heard, I am going to try to at least tell you how we got to where we are today with respect to this regulation. Okay.

FACILITATOR SALTER: Here you go.

DR. ZELAC: Terrific. I'm a senior member of NRC's medical radiation team. And that's why I presume I have been chosen to make this presentation besides the fact that I have been dealing in this issue for a good number of years now.

I am going to refer to several documents, which you will have available to you on NRC's website. And I wanted to tell you a little bit about something, how you can achieve those documents for your review.

Go to the NRC website, www.nrc.gov. There will be a tab "NRC Library." And when you click on that tab, you will then see another tab called "Document Collections." And, clicking on that, you

will see "Commission."

All of the documents that I am going to refer to today are under that "Commission" tab. They are either Commission papers or staff requirements memoranda, what the Commission tells us to do.

And for each of these documents, of course, there is an identifying number. And that number will begin with the year. For example, 05 means the document was prepared in 2005. And then there will be another number, which is what it is in the series, what document in the series.

So, with that as an introduction, here we go. SECY, which means a Commission paper, 05-0234. You can see what the title of it is.

There were several purposes for this paper. And in this paper, staff recommended that for all permanent implant brachytherapy medical events that involved the treatment site, the definition of a medical event should be in terms of total source strength variances, not absorbed dose variances. That is kind of fundamental to how we got started in this in the direction we were going.

Again, just to repeat, then, for medical events involving the treatment site, the medical events should be defined in terms of total source

strength variances; i.e., differences between what was achieved and what the physician had intended, not absorbed dose variances.

I am going to take a couple of minutes here and simply read a bit from that paper, which I think is instructive. And this is a quotation from the paper. It kind of gives credit and also tells how we got to this position. "During its March 2004 meeting, the ACMUI, our Advisory Committee," which you have heard about already, "considered the issue of defining medical events involving permanent implant brachytherapy. It concluded that the plus or minus 20 percent variance from prescription criterion in the existing rule was appropriate if both the prescription and the variance could be expressed in units of activity, rather than in units of dose as there is no suitable clinically used dose metric available for judging the occurrences of medical events."

To go on, "This paper discusses the basis for the current definition of a medical event, confirms that there was an appropriate basis for applying the 20 percent reporting threshold for medical events to each medical use modality."

That was the purpose, one of the purposes, of the paper, to look at all medical uses and make the

determination of whether this plus or minus 20 percent variance was applicable to all of them.

The conclusion was that it was with one exception, that the current dose-based definition be retained for the various usage modalities. For that one exception, permanent implant brachytherapy, the Commission was asked to approve the staff's plan to revise the medical event definition and the associated requirements for written activities to be activity-based, instead of dose-based.

And, as a result of that presentation to the Commission and their consideration of it, a staff requirements memorandum, SRM, was issued using the same numbering as the paper from which it came and using the same title. And in it, the Commission approached staff's recommendation.

Now we move on to what happened after that decision of the Commission for the staff to go ahead with "dose-based being" removed and "activity-based" being inserted "for permanent implant brachytherapy."

A proposed rule was published, SECY 08. And, of course, when I say, "published," I mean published in the Federal Register.

In this paper, staff provided as well as a modified rule for the use of total source strength

variance, rather than absorb dose variance for defining medical events for permanent implant brachytherapy treatments sites.

And in the staff requirements requirements memorandum, which followed this paper, the Commission approved the proposed rule for publication in the Federal Register for comment. And it was published, and there were comments.

In consideration of those comments and during that same time frame, there were some other events which did occur. And this resulted in a decision on the part of staff to publish a re-proposed rule, a modified proposed rule again for public comment.

In this particular SECY, staff provided the Commission with a re-proposed rule that added back a dose-based criterion for the definition of medical events for permanent implant brachytherapy treatment sites.

And, again, with your indulgence, I am going to read a bit from that paper because I think it is instructive, "During late Summer and early Fall of 2008, a substantial number of medical events were reported to the NRC.

"The staff reviewed and analyzed the

circumstances of and data from these events. Based on its evaluation of this information, including an independent analysis by an NRC medical consultant, the staff believes that a number of medical events that were reported in 2008 would not be categorized as medical events under the proposed rule published on August 6, 2008.

"This is inconsistent with the original regulatory intent. The original intent of the proposed rule was to clarify the requirements for permanent implant brachytherapy so that licensees would be able to identify medical events more easily and in a more timely manner.

"An unintended event effect of the proposed rule would have been that some significant events would not be identified, categorized, and reported as medical events." And it goes on, which I will skip.

So that proposed or re-proposed rule was then presented to the Commission. And the decision of the Commission was that it would not be published for public comment, that we would essentially go back to the drawing boards and have meetings like this to gain further insight from stakeholders as to the direction that would be appropriate for the Commission to go

with its regulations. And that's why we're here.

The Commission disapproved publication of the re-proposed rule and directed the staff to hold a series of public stakeholder workshops, then develop a different medical event definition for permanent implant brachytherapy.

And, again, once more I'm going to read from this directive from the Commission. It's I think instructive. "The staff should work closely with the Advisory Committee on the Medical Uses of Isotopes and the broader medical and stakeholder community to develop event definitions that will protect the interests of patients, allow physicians the flexibility to take actions that they deem medically necessary, while continuing to enable the agency to detect failures in process, procedure, and training as well as any misapplication of byproduct materials by authorized users.

"The staff should hold a series of stakeholder workshops to discuss issues associated with the medical event definition. Areas for discussion should include but not be limited to methods for defining medical events which continue to ensure the safe use of radioactive materials while providing flexibility to account for medically

necessary adjustments and the terms and thresholds for reporting medical events to the NRC and patients."

So that's kind of how we got to where we are today. And the large question, then, if you will, the challenge of what we are trying to accomplish from this point forward is to achieve a balance, an appropriate balance, between what we understand as the typical position of many in the medical field that a medical event should be linked with something that occurred to the patient which is of clinical significance.

And, on the other hand, NRC's need to have mistakes in the process reported where there turns out was a variance between what the physician had intended and what was achieved, even if there isn't an actual negative consequence to the patient to determine these process actions which result in what had been intended not being achieved.

I am offering simply a few of these acronyms and the need for medical events, SECY, Office of the Secretary; SRM, staff requirements memoranda, and reiterating what you have heard several times already.

We are here to listen. We are here to gather information. We are here to hear everything

that you have to say about this issue before we once again try to move forward and bring some resolution, some stability, to where we are in this process for now and in the future.

If you would like to at some point be in contact with me, there is an e-mail address, there is my telephone number. I would be more than happy at any time to hear from you.

FACILITATOR SALTER: Thank you, Dr. Zelac.

Our next speaker is Robert Dansereau. And, as Mike indicated, Mr. Dansereau is filling in for Cheryl Rogers. And we really appreciate him helping us out at the last minute.

Mr. Dansereau is currently the Assistant Director of the Bureau of Environmental Radiation Protection at the New York State Department of Health. He has 18 years of experience in the regulation of radioactive material and X-ray equipment and 15 years of experience in nuclear chemistry and handling radioactive material under broad scope research and development radioactive materials license.

MR. DANSEREAU: Good morning. As Mike said, I'm here to fill in for Alice Rogers and did quite a bit of work in gathering the information I'm going to present to you.

She sent out a survey to the Organization of Agreement States, which is those states that have entered into agreement with the NRC to regulate materials in their states. There are currently 37 agreements states.

She did this survey in preparation for this meeting. And she received 15 responses. I'm just going to summarize that. Of the 15, 12 states reported that they did have permanent brachytherapy events in their state. In terms of regulations, all the states either have identical or slightly more restrictive requirements than the Commission.

In terms of their inspections, all inspectors look for the written, WDs, written directive, and the procedure for the written directive.

Twelve of the states, their inspectors routinely review patient charts as part of their inspection. They feel that, nine of the states feel that, the authorized AMP, authorized medical physicist, is aware of the reporting criteria. Five states say that they are waiting for NRC for additional guidance.

This question asks, you know, what do you consider a medical event in your state. You can see

from the responses five states said the D90 criteria, one D80, one D100. A few said a combination of the two. Others suggested focusing on physics errors. And eight said focus on physician errors. There were some other responses we looked at, too hard to summarize here.

This was an example. If a dose to an organ or tissue is outside the target volume by more than 120 percent, do you consider this a medical event? Seven said yes. One said no. One said, "We use the criteria we use as 150 percent to a small volume." And six said, "Other criteria," which was somewhat a combination of -- excuse me. It was "We rely on the facility, the physician, the physicist to evaluate whether this would be a medical event or not.

And when asked, "What was your state's position on the medical event?" -- they could select from the following options -- two said, "Prostate medical event is not a high priority because they're usually successful events, successful treatments.

Ten are relying on licensees to report. Eight felt that most of the authorized users are aware of the medical event criteria. Nine felt that the authorized medical physicist is aware of the medical event criteria. Five are awaiting for additional NRC

guidance on the issue. And six have revised their inspection procedures following the Veterans Affairs hospital events. And there were three other responses.

In summary, we see the various interpretations of medical event for the state regulatory folks, but the regulatory requirements are very consistent. I believe we are looking at a need for some training and guidance in general. That might be for the licensees as well as regulators because the regulators, we didn't see 15 responses saying that they felt that the authorized medical physicist and authorized user are aware of the criteria. So I think there is a training issue there.

The next statement is the last question on the survey asks, do you have any other information or thoughts on this idea? I thought it was interesting that no states mentioned the concept of reporting based on activity.

Wisconsin also -- this is an interesting thing that Alice Rogers and her staff did. They did an 11 licensees review, a total of 1,200 cases since 2003.

And they identified, the licensees identified, less than three percent meeting the

medical event based on the dose criteria. And that might suggest that the dose-based criteria works.

Thank you.

FACILITATOR SALTER: Our next speaker is Dr. James Welsh. And since 2007, Dr. Welsh has served as one of the radiation oncologist representatives on the NRC's Advisory Committee on the Medical Uses of Isotopes.

He is currently professor of neurosurgery, radiology, and radiation oncology at Louisiana State University Health Sciences Center in Shreveport and is also an attending radiation oncologist with the Willis-Knighton Hospital, also in Shreveport.

Dr. Welsh earned his medical degree at Stony Brook School of Medicine and then completed his residency training in radiation oncology at the Johns Hopkins Hospital.

DR. WELSH: Thank you, Susan. Thank you all NRC for conducting these workshops, which ACMUI and many others have suggested and recommended for quite some time. I expect this will be a very fruitful couple of days.

Just to start off my presentation, I'm going to review some interesting and relevant material from our annual ACMUI medical events analysis.

In 2010, we analyzed the medical events that were reported that year and not necessarily exclusively occurring in that year. There were 26 medical events in the 400 series, the manual brachytherapy series, involving 75 patients. Sixty-nine were prostate permanent implant brachytherapy. Eight of these were overdoses.

One was excessive dose to normal tissue. Another one was due to incorrect seed activity. And, importantly, one of the initially reported overdoses was retracted subsequently based on post-implant dosimetry, which underscores the fact that this is not an exact science.

The rest of those reported in this series were underdoses. Two of the underdoses were subsequently retracted and were found not to be true medical events, just as we have asserted could happen over and over again because of the fact that the prostate does change its size and shape following an implant.

In these two cases, the prostate apparently swelled. And upon further reevaluation, the final dose was within 20 percent and was not considered to be a true medical event.

In 2010, a very unusual occurrence was

reported. It was initially considered a medical event but then subsequently retracted. D90 was calculated as less than one percent, which would seem quite unusual, quite absurd. Something obviously has gone wrong. But it was not considered a medical event because 39 out of the 41 seeds were placed within the so-called target. All of these seeds were implanted within a few millimeters of the isoline according to the analysis. The authorized user stated that the seeds could have been placed in a better location. It was attributed to poor image quality.

But this is something that we or I personally have said could never happen. And many of us have asserted that this concept of all the seeds being bunched and challenging any of the previous ACMUI definitions just is unrealistic. It's not as unrealistic as I initially thought. It did happen at least once here.

Well, the fact is that the majority of the reported medical events in the series documented in 2010 were based on dose; for example, D90. The question obviously remains, would these labeled medical events still be considered true medical events if we used a more appropriate definition, such as the definitions or activity were source strength

exclusively.

Importantly, many of these reported medical events occurred earlier and were reported in the 2010 period. And apparently many states are reviewing prostate brachytherapy implant series over the past several years.

And I can tell you that although our reported terminated in late 2010, the last portion of 2010 included a good number of medical events that occurred in the years prior. It's just that the analyses have not been completed by the time we did our report. And I suspect that there will be very many more in the year to come because of this.

Returning to the important point of our subcommittee's analysis on medical events, the subcommittee has asserted in the past and continues to assert that activity-based metrics remain the preferable means of defining medical events.

Dose-based metrics are fraught with challenges and difficulties. We are all aware of the VA events and the re-proposed rule SECY 10-0062. And these have not changed our opinion that the original ACMUI definition remains valid.

Dose-based metrics are fraught with challenges and difficulties. And you have heard

before and you will hear again challenges that are anatomic because of volume changes and shape changes in the prostate due to edema, atrophy, hormone therapy-related changes, hematoma. And whenever there is a volume change, this will affect dose because dose is defined as energy per unit mass. The mass is related to the volume.

If the volume changes, the denominator changes. The dose changes. And this is a fact that we have reiterated over and over again.

Most members of the subcommittee feel that the term "medical event" probably should best be reserved for occurrences that are of true medical significance. And, therefore, the definition should be sensitive enough to detect potential harm to a patient, acknowledging that harm can be due to overdoses to sensitive tissues and structures but also that harm could be construed as underdose and, therefore, not curing the patient of the cancer that the treatment was intended to do.

We also acknowledge and understand and appreciate that the NRC would like a definition that is capable of identifying trends and patterns that might lead to patient harm. But it is also important to keep in mind that this is medical event definition.

And whenever you are talking about something medical, the reality, unfortunately, in this country's medical and legal environment is that something labeled as a medical event triggers unnecessary reactions. And the term "medical event" does have a particularly negative connotation. And patients who misunderstand and attorneys who capitalize on this misunderstanding will take advantage of inaccurate or inappropriate definitions.

The subcommittee feels that post-implant dosimetry is important and should be performed. There was unanimity on this point. However, the subcommittee did have some controversy and internal debate about any deadline.

The 60-day timeline that was proposed is particularly controversial. A couple of obvious points are that patient-related factors, such as the patient not showing up for the planned post-implant dosimetry clearly should not be a medical event.

But even if a 60-day deadline is opposed, a slight delay beyond 60 days probably should not be labeled as harshly as a medical event. It is acknowledged that you can't have the first, insisting that dosimetry be performed, without some kind of a deadline because then an inspector or any regulator

would come by and say, "Where is your post-implant dosimetry that is mandatory?"

Somebody could say, "Well, in this particular case, we were going to do it at 2 years, rather than at 60 days." So it does make sense to have some type of a deadline. And most of us were not opposed with the 60-day figure with the exception that it probably should not be as harsh as a medical event should it be violated.

The subcommittee felt that perhaps separation of permanent implant brachytherapy into two categories might be helpful. The first would be that category in which significant rearrangement of the implant location can occur during completion of the surgical procedure, as in lung implants or mesh implants, and those procedures that do not; for the most part, prostate implants. So, in essence, this would be non-prostate and prostate.

Another point that the subcommittee identified as deserving some review is this, the so-called 50 rem 50 percent rule, keeping in mind that 50 rem is a very, very small dose compared to the therapeutic doses that are prescribed.

If we're prescribing 150 gray for a prostate, for example, this is a tiny amount, less

than one percent. A 50 percent overdose could be very inconsequential medically to a patient when we're talking about doses that are very low to begin with.

For example, we do not always contour the femoral head, penile bulb, or small bowel, but if we did and seed was placed just a few millimeters to the right, left, superiorly, inferiorly, you could calculate the dose to the femoral head as being maybe 50 percent higher than it would have been and possibly wind up in a medical event situation, even though we're talking about doses that are extremely low in the first place and not likely to cause any harm to a patient.

Additionally, we recommend that the units in this section B reviewed and revised, but overall it might be preferable to just drop this holdover from a prior era.

ACMUI and the subcommittee acknowledge that the NRC may continue to insist on a dose-based metric, despite our recommendation. We do advocate and continue to advocate activity-based, source strength-based metrics and definitions. However, if an alternative is sought based on dose, we propose this for the target, wherein D90 is less than 70 percent of the CTV and, a Boolean AND, less than 5

percent of the sources occupy any octant of the PTV except by intent, which would be documented in the written directive.

For normal tissues, the bladder and rectum D5 would exceed 150 percent of the prescription dose or the D5 of the urethra would exceed 150 percent of its value on the planned and approved dose distribution.

This definition certainly would catch any event where all of the seeds were bunched, as in the hypothetical scenario that was proposed a year ago. And apparently something similar has occurred and reported in 2010.

This definition would not signify as a medical event any implant in which the sources are missing an octant provided the dose coverage is above 70 percent. And it would not signify as a medical event anything that an octant is devoid of seeds if it is intended, for example, when the authorized user wants to spare the anterior portion of the prostate.

I will conclude by stating some of the obvious points about the overall safety of permanent implant brachytherapy and prostate brachytherapy, in particular.

Out of 20,000 some odd procedures, there

were 69 medical events. And this amounts to 0.33 percent. It's a low figure, but it's not low enough. There were far fewer patients that were actually physically harmed by prostate brachytherapy than even this apparently low figure would suggest.

0.33 percent is superficially low, but it's probably grossly beyond what the true potential harm is. And, as our previous speaker has mentioned, three percent in the series analyzed in Wisconsin is far, far above what many of us who practice brachytherapy would consider realistic.

So it is safe, but the definition is putting some challenges on our practicing community. And, as an example of how important this challenge is, in 2004, there were approximately 190,000 prostate cancer treatments and 41, almost 42 thousand seed implants. About 22 percent of patients who got treated were done so with permanent seed implants.

If you fast forward just 5 years, keeping in mind the intervening VA series and the publicity surrounding that, there were 219,000 cancer treatments, prostate cancer treatments, but only 17,000 permanent seed implants, which means a significant drop from 22 percent down to 8 percent. And this might mean that a very important, valid,

safe, and effective treatment for prostate cancer is slowly but surely vanishing right before our eyes.

We understand that there are competing modalities that might be causing this, but I think many of us can't escape the conclusion that the reported series must have something to do with this, too.

So it is imperative that we get this definition correct. And hopefully we will come upon some important points that will help us over this workshop.

Thank you.

FACILITATOR SALTER: Thank you, Dr. Welsh.

All right. Next I would like to call Dr. Michael Hagan to make his presentation. Dr. Hagan is currently the Veterans Health Administration's National Director for the Radiation Oncology Program. He's a graduate of the United States Military Academy in West Point, New York and earned a graduate degree in nuclear engineering health physics and a Ph.D. in biophysics, radiation biology, both from the University of Illinois in Urbana.

He completed his medical degree at Baylor College of Medicine in Houston, Texas and is board-certified by the American Board of Radiology.

I would remind you that full bios for all of our panelists are in your packet. And I believe presentations are out on the table if anybody would like a copy and didn't get one.

DR. HAGAN: Thank you. Thank you for the introduction. Thank you for inviting me to participate in the panel.

In the interest of time, I'm just going to launch into a presentation I usually get through in seven minutes with one more cup of coffee than I had this morning. And hopefully it won't be too much over that.

You heard about the 2005 activity of the ACMUI. In 2009, after the VA's initial evaluation of implants at Philadelphia, I recognize that not only had they used an absorbed dose metric that the ACMUI had recommended against, but they had used it in a flawed manner.

And so the VA assembled a blue ribbon panel of the country's experts in prostate brachytherapy. That panel was responsible for thousands of implants among them and over 500 papers on prostate brachytherapy.

The panel agreed with ACMUI's recommendation in 2005, recommended that the VA

incorporate an activity metric and defined that metric for the Under Secretary, at the same time recommended a reevaluation of Philadelphia applying both the activity metric and a D90 evaluation that attempted to correct for the flaw that was used in the initial evaluation.

This morning I want to show you why that panel of experts condemned the VA's absorbed dose metric and why it supported ACMUI's recommendation in 2005.

The first slide shows you the related reporting requirements for manual brachytherapy procedures. Note that the reporting of deviations greater than 20 percent is also accompanied by a requirement to report excess dose to nontarget tissues.

I will show you that while the first of these requirements is usually addressed by an activity metric, it's nearly impossible to approach using an absorbed dose metric. But the second piece, nontarget tissues, can be easily handled with an absorbed dose metric. And, in fact, this has been done for prostate brachytherapy.

The flawed evaluation that the VA used was to use a D90 and to use a D90 applied to a set of

images that were inappropriate. D90 is a global estimate of prostate dose, of the many absorbed dose measures examined in the critical literature. Minimum dose of 90 percent of the target tissue; that is, the D90, has been the most useful for clinical reporting but has been reiterated as late as the Fall of 2009 by task group 137 from AAPM that the use of D90 and recommendation of D90 is a clinical recommendation and is not to be used for regulatory evaluation. In fact, the earlier report from the task group 64 specifically stated that within the task group report.

Here in front of you is a prostate implant that identifies and demonstrates some of the parameters that are problematic for the application of D90. While this particular implant has a D90 of 95 percent of the prescription dose, note that the interior of this prostate, more than half of it, is being dosed at greater than 150 percent of the prescription dose.

The reporting requirement is that we dose within 20 percent of the prescription dose. Using D90 makes you believe that the D90 value can be within 20 percent of a prescription dose, but the actual physical dose to the prostate is very heterogeneous, involves substantially greater dose than the

prescription dose.

Also, as an aside, note that this particular dose distribution is valid only for one day in the lifetime of this implant. That point will become significant on later slides.

The other thing to notice here, two things, one is that D90 is based on a red contour that you can see there. And that is a physician's guess at where the prostate ends on this CT. So while the CT shows bony anatomy very nicely and can show soft tissues to some degree, demonstrating where the prostate starts and stops is such a problem that we have studied that within the literature as a separate entity of itself. And I direct you to Robert Lee's publications on that issue.

Also note that the separation between the D90, which represents excellent coverage, that green isodose, which is outside the prostate, and the blue isodose, which would indicate a medical event, is less than three millimeters, one to two millimeters in places. And, yet, the amount of swelling that we would see in a prostate can easily be five to six times that amount.

The next slide shows you a palladium implant, where swelling is the issue. Here the D90

was determined immediately following surgery. And, although the prostate was only increased to 35 cc, 20 percent from the volume study, you can see that this reduced the D90 to 80 percent, which makes it reportable.

Thirty days after the implant, a redetermination found the D90 to be 99 percent. So at 30 days, this implant was not a medical event. Yet, the AU, the authorized user, has done nothing in the interim. So what if this patient didn't come back at 30 days? Was this a medical event because of the day one evaluation? That was the flawed application in Philadelphia.

Which D90 actually represents the actual dose delivery? I mentioned that these images occur as only one point in the trajectory of the dosing of the prostate. For palladium, most of the dose was delivered in the first 17 days. Over half of it has been delivered long before this patient shows up for the 30 days.

So which of those two images reflected the dose that the prostate received, the day one, medical event criteria, or the day 30, which did not?

Okay. Here is a similar evaluation of an I-125 implant. Here immediately post-op, there is

quite a bit of edema. But the D90 is 94 percent because of the physician's design. However, when this patient comes back at 30 days, the D90 is now 120 percent. Is this a medical event?

I present right below it the current criteria for the only phase 3 cooperative group protocol for prostate brachytherapy that asks the physician to design D90 to be between 90 and 130 percent.

So that is considered a per-protocol excellent implant. And there is no practitioner that would argue that a D90 of 120 percent is a defective prostate implant.

So these global measures have several properties that make them difficult for regulatory evaluation, highly variable through operator dependence; i.e., the contouring.

Part of it will reflect clinical outcome; that is, our best estimate of these global measures that track clinical outcome, is the D90, but the validity of that tracking is minimal. And the ability of D90 to reflect clinical outcome has been poor every time we have examined it within the literature.

It also lacks precision, this 20 percent precision, which was required for regulatory

evaluation and specifically has been commented on in terms of clinical but not regulatory measures by the AAPM relevant task groups.

However, prescribed dose, the definition which is currently in the part 35, allows 2 categories of dose for manual brachytherapies: total source strength time exposure time or dose relating to absorbed dose.

So what is this activity metric identified by ACMUI, recommended by the VA's blue ribbon panel, and also presented to the commissioners by a delegation from ASTRO in the spring? Total source strength, activity-based metric, measures the physician's performance, which you have heard a couple of times already from the platform this morning.

Prior to completing the implant, the authorized user identifies the treatment site and the total activity to be inserted. During the implant and afterwards through imaging, the authorized user determines where seeds have been placed.

If 20 percent have been placed outside of that treatment site, then that is a medical event by the activity metric. It's a simple one to apply.

Here on these two slides, examples of how the activity metrics rises to the occasion. This is a

practitioner who has decided to spare the anterior prostate, has also been mentioned this morning.

You can see on the far left some pathologic data that support that notion. This clinician has placed his seeds in a predetermined pattern, somewhat in the middle. The actual CT shows the seed placement with the anterior sparing on the right. And for this implant, 100 percent of the seeds have been placed within the target site. The D90 for the entire prostate is about 69 percent for this particular prostate.

This practitioner had no desire to treat this patient based on a D90. And the pre-operative consent and the operative note both reflect that the physician had no intention of treating the anterior prostate of the patient and told the patient that prior to the procedure.

So this is an implant conducted not based on absorbed dose but based on seed positioning. And although I may personally disagree with that practice, this patient five years later has an undetectable PSA. So you certainly can't argue with the outcome and the logic for it, and this is not unusual in the practice of brachytherapy today.

The next slide shows two cases of

physicians who differ quite markedly in their particular style. The first puts all of the seeds within the prostate and actually uses seeds of a different activity around the core or the urethra, making it nearly impossible for a post-implant evaluation to determine D90 with any accuracy and also opening up the change that come with the swelling of the prostate. So the swelling of the prostate produces large D90 changes when essentially all of the seeds are placed within the prostate or the target volume.

Below that shows the style of a practitioner that uses seeds of a greater activity, places many, if not most, of the seeds outside of the prostate. The D90 is very insensitive, then, to edema changes in the prostate, but in each case, the activity metric works very nicely.

Both practitioners have defined the treatment site in their written directive and in their consent form. Both practitioners have in the operative note evaluated the seed placement with regard to their intent and signed in writing that the seed distribution was as they applied it.

In both cases, the series from these institutions do very well, although you can see there

are radical differences in these physicians' designs.

So, in conclusion, for the implants to work and be evaluated successfully in terms of our regulatory metric, an absorbed dose metric lacks the objectivity and the precision to be able to apply this plus or minus 20 percent.

The correct placement of seeds alone is what we can hold the authorized user to account for. This is what he can control in the operating room. Controlling the dose depends on the volume changes of the prostate. And controlling the dose on any particular day is determined by the time course edema resolves after the implant. So 60 days will work for most patients in terms of resolution of edema, but there are some for which that will not.

The estimation of edema half-life goes from 4 to 30 days. So we need a metric that applies to everyone. Hold the authorized user to account for the use of the byproduct material as he intended, not to our favor, dose distribution.

Thank you.

FACILITATOR SALTER: Thank you, Dr. Hagan.

Our next speaker is Dr. Ronald Ennis. Dr. Ennis currently serves as Director of the Department of Radiation Oncology at St. Luke's-Roosevelt Hospital

in New York City. He is also an Associate Director of Continuing Cancer Centers of New York and Associate Professor of Albert Einstein College of Medicine.

As a radiation oncologist, Dr. Ennis has treated over 1,500 prostate cancer patients with permanent implant brachytherapy and published many articles on prostate cancer, including several on prostate brachytherapy.

Dr. Ennis has also served on the ASTRO Government Relations Committee since 2006.

DR. ENNIS: Good morning, everyone. Thank you for inviting me to participate in this panel. Thank you for the opportunity to make a statement on behalf of the American Society for Radiation Oncology. I am Dr. Ron Ennis, as you heard. And you have heard my bio a minute ago.

So ASTRO, whom I am representing, is the largest radiation oncology site in the world with over 10,000 members who specialize in the treating of patients with radiation therapies.

As a leading organization in radiation oncology, biology, and physics, the society is dedicated to improving patient care through education, clinical practice, advancement of science, and advocacy. ASTRO's highest priority has always been

ensuring patients receive the safest, most effective treatments.

ASTRO believes the current definition of a medical event for permanent prostate brachytherapy when it arrives as an estimated absorbed dose is particularly problematic and requires practitioners to report events that are medically acceptable.

Under part 35, section 35.3045, as we have heard, it is deemed a medical event if the total dose delivered differs from the prescribed dose by 20 percent or more.

ASTRO believes that such a rule is not appropriate for prostate brachytherapy. If the NRC definition is rigidly applied, many medically acceptable and appropriate implants will be deemed medical events, treating unnecessary patient apprehension about physician quality.

Furthermore, we are concerned that dose-based measures are medically inappropriate and encumber a regulatory body, such as the NRC itself and the licensing bodies with clinically irrelevant and costly investigations.

A dose-based definition of medical event is not suitable for prostate implant brachytherapy. It should also be noted that a medical event is a

significant event in the life of the physician. The regulatory scrutiny internally within the department, the hospital, and externally is probably appropriate for serious events that have actually occurred.

One can envision physicians deciding to avoid such problems to the detriment of the patients at large. Prostate brachytherapy is an outstanding treatment for prostate cancer with extremely high success rates and very low complication rates compared to most of the other therapies that are available.

Furthermore, in our current medical environment, we cannot ignore the fact that it is by far the most cost-effective treatment for early localized prostate cancer. We run the risk of regulating this extremely effective and -- both effective from a clinical and cost-effective point of view treatment regulating it out of existence without being more careful about the regulations.

It is important to also understand that normal cells tolerate radiation better than cancer cells. So some exposure of normal tissues to radiation doses are perfectly acceptable. This is how radiation is a successful treatment.

Safe levels of radiation depend on the doses, the duration of the treatment, the tissue size

that is exposed to radiation, and the actual tissue of organs. Different tissues have different radiation sensitivities.

There is also inherent variability in the radiation sensitivity of individual patients, most of which we still do not understand. The only way to know what is actually safe or dangerous and, thereby, inform a medical event definition, is to study patients, what happens to them, and try and determine the relationships between dose, volume, tissues, and individual variability.

At present, we do not have enough information of a sophisticated enough nature and a definitive enough nature to make any strong recommendations. Even though D90 that we have talked about before is not proven to be an absolute definition of success or failure, many patients, many patients with a D90 less than the holy grail of 90 percent are cured and do perfectly well. Many studied in the literature show D90 to be a predictor, but there are actually several that do not and show other dose levels or no dose level at all as a good correlation.

So this is an evolving science. This is not given to us as a "This is how to do it, and it's

end of story." It is an evolving science.

Similarly, when it comes to dose to normal tissues, the doses that are safe or unsafe are very poorly defined. There are some papers that suggest certain doses, but they really are very poorly defined.

So we need a definition that really captures what we know now. And it could be obviously modified in the future. But we need to pay attention to what we do know and what we do not know. We do not know in a well-defined way what dose is actually safe or unsafe and for most of the circumstances.

This is what allows practitioners in good faith to have different styles, as you heard about before, different ways of applying that literature to their patients, and different types of patients. And not only is the physician involved with the patient as well, patient may be more concerned about one toxicity versus another. And I might, therefore, decide to do my implant a little bit different for him.

So, for example, I think these couple of figures will be helpful here. So this is a prostate demonstrating the prostate and the typical prostate cancer, where there is more than one tumor in the prostate, also typical in that you see the tumors are

on the periphery or the edge of the prostate.

Now, the normal tissues are very close to the prostate. You see those blood vessels and nerves on the left and right corners there. And those are important for sexual function of the rectum, which is not on the cartoon, is right behind the prostate on the bottom there. But right at the edge there would be the rectum.

Now, if I had a patient, for example, who was very concerned about sexual function and wanted this treatment for that, I might purposely be careful to not give any dose or very little dose to those neurovascular bundles. Well, that might cause me to compromise my D90 a little bit, but for the patients' goals, that might be the right thing to do, especially if I could be pretty comfortable there is no cancer over there based on neuroimaging or biopsies that were done. If I am restricted from that flexibility as a practitioner, that's not just to my detriment but to the patients' detriment.

Hopefully you can notice the difference in the size of these two prostates. And, as you have heard before, the change in the size and shape of the prostate, as I am trying to demonstrate in these cartoons and as others have mentioned before, is a

crucial issue in defining things by D90.

The missing piece, just to clarify, is the dose from each seed is very intense, but the energy and, therefore, the depth of penetration is very low. Each seed's dose travels only a few millimeters.

So it is very sensitive to positioning. And this is a crucial issue in trying to use a dose-based measurement because small changes in the size or shape of the prostate, small changes in the location of a particular seed can change these metrics dramatically. You have seen some examples before.

In this example, the prostate swelled a tremendous amount. Now, I as the implanter of this patient -- for example, this is just a cartoon, of course, but I cannot predict how much swelling an individual patient will have. So it's not just that it might swell, it might not swell. I could easily have an event through something I have absolutely no way of predicting and absolutely no control over.

One patient's prostate might swell five percent. If I implant his intensely because I am afraid he is going to have a 30 percent edema, he is going to have an "overdose" depending on how you define that; similarly, someone whom I implant less intensely but then has a marked increase in the edema

of the prostate.

So we have to when we do our implants understand and plan accordingly. And, therefore, we need a fair amount of flexibility in the dose prescribed to do a good job for each individual patient.

The cartoon also here demonstrates the red spots, you know, the hematomas, but they are actually much larger than that and can space seeds apart.

The other thing that is important to understand here is how that the tumors are on the periphery of the prostate. And that is crucial because the tissues are also on the periphery.

So I want you to understand the delicate balance a physician is trying to achieve when he implants or she implants seeds in the prostate. And the dose, you want to confine the dose to the prostate. You want to get the tumors with very high doses. But you do not want too much dose to the normal tissues.

And that balance is challenging. And we need metrics and definitions that are flexible enough and forgiving enough to allow this highly effective treatment to move forward and advance.

Just to further clarify some of the points

made briefly before, these are just to show you some images just to put you in the physician's position to understand.

So on the top are two ultrasound images. And these are pretty clear. So I think most of us, even if you had not seen this before, could outline a prostate accurately. But I challenge you to look at the images on the bottom, in the bottom left, and tell me where you think the prostate starts and ends.

Now, I can tell you that if I contour that one way, a D90 will be very different than if I contour it in another way and all in good faith. Different people, as alluded to before, -- Robert Lee has shown this in the literature -- can in good faith contour the prostate differently and get very different dose metrics.

Similarly here -- and this is if you look at the top of the ultrasound. So this is towards the apex or the bottom of the prostate. And, again, where that apex is, how you define that on your ultrasound will have a huge impact on what you do. And it's ambiguous.

That doesn't mean this treatment shouldn't be done, of course, but we have to understand the realities of what we're dealing with and make sure our

definitions match, similarly on the CT at the bottom.

So finally, as mentioned before, the dose-based definitions are intrinsically different because of the edema problem and the change in prostate volume and shape over a period of time. The day one CT scan will give a markedly different dosimetric outcome than a day 30 implant or a day 60 post-implant CT or day 90 post-implant CT.

And, again, as yet, it's not clear what is the optimal time that that should be done. There is tremendous controversy in the field among various practitioners. And there are arguments for and against the different time intervals.

So, to define a medical event on the basis without some science behind it, without clear definitions seems inherently fraud. Therefore, instead of a rule based on absorbed dose, ASTRO recommends a target-based definition, with 20 percent of source strength implanted outside the planting target volume as an appropriate definition of a medical event for regulatory purposes.

This is what is in control of the practitioner at the time of the seed implantation and is independent of the problems noted above regarding prostate volume changes and imaging issues.

ASTRO believes that a target-based definition is a necessary change to ensure that those implants that could potentially cause serious patient harm are characterized as such and want those identified but that those that are not -- but not defining those that are actually medically acceptable as medical events.

We appreciate the NRC's deliberations on this issue and look forward to working with the Commission to revise the definition so that patients have access to the medically appropriate procedures they need.

Thank you.

FACILITATOR SALTER: Thank you, Dr. Ennis.

Our next speaker is Dr. Herbert Mower. Dr. Mower currently serves as the Director of Radiation Therapy Physics at the Lahey Clinic located in Massachusetts. He received his doctorate degree from MIT and is board-certified in radiation oncology physics by the American Board of Medical Physics and in therapeutic radiological physics by the American Board of Radiology. He is a fellow of the American College of Medical Physicists and the American Association of Physicists in Medicine.

DR. MOWER: Thank you.

There were a few questions that we were asked. And I would like to address those very briefly. Should the regulations have a specific section for prostate implant brachytherapy, rather than combined with all of the permanent implant brachytherapy? The response of the AAPM is no. It should apply to all, to any permanent implant brachytherapy, not just to prostate.

Should the criterion for defining a medical event for permanent implant brachytherapy be activity-based only? AAPM strongly says yes on this and that the written directive should be at the time of the implant. This is because prior to the implant when the doctor first looks at the prostate and sees it ordered, you may see one size but due to taking various hormones and whatnot, the size of the prostate may change in between.

And what you want to treat on the day of the implant is what is there on that day, not what was there two, three, four, six, eight months prior to that.

Also, we do frequently do real time planning in the operating room. The physician is, therefore, aware of exactly what it is that he is trying to treat at that time.

Should the criterion for defining a medical event for permanent implant brachytherapy be dose-based only? No says the AAPM but activity-based.

Should it be a combination of the two? No. Activity-based.

Should the NRC require training on how to identify medical events? Our feeling is no. This is part of what is done in the overall training to our staff each year. And it's written up in the licensee's license as part of their training program, which can be reviewed by the NRC, but there is no reason for the NRC to be doing that training.

Major professional organizations have recommended standards for when a dose to the treatment site for permanent prostate implants is assessed. NRC staff is considering adding a time requirement to the regulations for this purpose. What is the appropriate time frame?

And we said, for various reasons, that it should not be a time frame. This can vary from the same day to one month depending on quantification availability for individual licensees, whether or not a patient is able to make it back at a future period. So you may decide to do it earlier for one patient than another.

We have a fair number of patients at our institution that come from out of the country. And trying to target them to come back at a specific date or a very narrow range of dates for a follow-up CT and evaluation is often difficult, if not impossible.

And then if you had something like 9/11, what does that do to the whole thing? Does everybody end up with a medical event because all the airplanes are canceled for several days and people can't get to your facility?

One of the other things the AAPM would like to recommend to the NRC is that as we go forward, we use the term "source strength," rather than "activity," current standards for the professional international society organizations.

And supposedly we went to the SI Unit several years ago. And we would kind of like to see that this not be on the level of the United States as things were when we went to the scientific units and whatnot, rather than English units, for various things, which, of course, we all know happened legally by Congress.

We changed over to the metric system just prior to the war, Civil War. And we haven't quite caught up yet in the United States with what we

decided to do way back then. And we would think that we should be a little bit faster in going with the scientific units.

FACILITATOR SALTER: Thank you, Dr. Mower, for getting us back on time. Our next panel presentation will be from Maureen Eisner. Ms. Eisner is presently the Director of Patient Advocacy and Medical Ethics at Westchester Medical Center and is on faculty at New York Medical College and William Patterson University.

She earned her Master's in health advocacy from Sarah Lawrence College and has been involved in patient advocacy and bioethics for almost 20 years. She participated in the first clinical ethics credentialing and privileging project in the United States and currently serves as the Co-Chair of the Ethics Committee at Westchester Medical Center.

MS. EISNER: Thank you.

I just wanted to start with the definition of a health advocate. According to Sarah Lawrence College, advocates support and promote the rights of the patient in the health care arena, help build capacity to improve community health and enhance health policy initiatives focused on available, safe, and quality care. And I think that is the reason that

everybody is here today.

Activity-based versus dose-based. Certainly the objective here I believe is protecting the patient from harm while trying to give curative treatment, which is the primary objective. If harm has occurred, disclosure should be mandated unless it goes under therapeutic exception. This is certainly as disclosure to the patient.

If therapeutic exception exists, then this should be disclosure to a surrogate always. Dosing needs to be high enough to be curative but with the least amount of complications.

Minimum activity and maximum activity of the seed should be used as part of the consideration of how to handle corrective treatment in the future care of the patient. And I think that is why it is so important to look at both.

Definition of a medical event should be a combination of activity and dose-based criteria.

On the issues of training time and other requirements, training needs to be a necessary requirement for defining a medical event. Standards need to be analyzed as to defining a medical event by harm, benefit analysis. I think we heard by the survey that there were some inconsistencies to the

understanding of what a medical event was by one of the presenters.

When trying to identify time requirements, time frames should include minimum and maximum definitions from the time of dosage. Regulations should have a specific section for prostate implant brachytherapy, rather than combining it with all other permanent implant therapy as there are distinct risks and issues involved for the prostate implantation being that it is so close to other vital organs.

Going to inform consent. And I think I heard some issues about the physicians feeling somewhat uncomfortable with the definition of a medical event because it had sort of a negative connotation to that. I think part of that is part of the informed consent and really having the patient understand what the issues are here and having a more transparent view of it.

So patients need to have a clear understanding that placement of seeds can move and dosing can be difficult. So lower doses may need to be given, and additional therapy may be needed, as opposed to higher dosing, where if there is a medical event, organ damage may not be reversible.

Transparency should always exist,

understanding the risks of exposure of radiation to self and others, and patients should be empowered to make an informed decision based on outcome, quality of life as it relates to the specific patient's lifestyle and preferences; risks; benefits; and, again, lifestyle changes.

Questions that all physicians should answer when they are discussing this therapy with their patients. What were the clinical findings where treatment options exist? And what happens if the patient doesn't get treatment? Purpose or rationale for the recommended treatment? What is involved for course of treatment or procedures? How often will the patient need treatment and how many treatments? Benefits, side effects, precautions to be taken? What happens if the treatment does not work? What treatments will be available if this treatment fails? How are the side effects different for different treatments?

Surgical versus radiation therapy. The outcomes, are they equal in terms of curing or controlling the cancer? How will each impact on quality of life? Certainly issues of incontinence and impotency.

Conflicts of interest and additional

issues. There need to be stringent guidelines to reporting and transparency so there is not any inclination not to report an event that may cause harm to the patient.

A conflict may exist because the physician needs to report the medical event to the referring physician so that he or she can report to the patient.

There may be concern that this may impact future referrals. And also presently there are some insurance companies that are not paying for this therapy, which is limiting access of patients that can benefit.

Thank you.

FACILITATOR SALTER: I would like to thank all of our panelists. Why don't we give them a round of applause for taking the time --

(Applause.)

FACILITATOR SALTER: -- to prepare their positions and that of their organizations?

What we are going to do right now is take about a 30-minute break. We will get back together at 10:45. And at that point, we will begin the open dialogue between the panelists. So get some refreshments, and we will see you in 30 minutes.

(Whereupon, the foregoing matter went off

the record at 10:09 a.m. and went back on the record at 10:46 a.m.)

FACILITATOR SALTER: Welcome back. The second part of our morning program I think is going to be an exciting one. The panelists, free from their requirement to provide a formal presentation, will now be able to engage in open dialogue with each other.

And, again, for those of you -- I know we had some people join us after we had some of our opening remarks. I just want to remind everyone that the morning part of our program is for the panelists, both to present and engage in a dialogue, and for the audience to listen. We won't be going to the audience for comments this morning, but we have all afternoon to do that.

If you would like to speak this afternoon, we ask that you fill out a blue card. And you can drop it off at the front desk. There should be plenty of them on the table, but there is also an additional supply out in the back. You can also sign up to get on the NRC mailing list for issues related to medical regulations.

If you would like to get on the mailing list but you don't want to make a comment this afternoon, we have yellow cards for that. But if you

have any questions, you can always ask the ladies at the front desk, and they can explain it to you.

But, most importantly, if you want to make a comment, please fill out a blue card. Again, you will be able to fill out a blue card this afternoon. So if you decide later on you want to speak, that's fine. You have time to fill that out. But if you know you do, we ask that you fill them out and drop them off at the desk before lunch.

So, with that, it looks like we have everyone. We have the webinar back on. All right. So what we're going to do is this is really an open dialogue for the panelists to bring up issues and respond to each other, but we are going to start.

I am going to just kick it off with Dr. Hagan. I'm going to ask him to elaborate on issues related to dose to other organs and tissues.

DR. HAGAN: Thanks, Susan.

- PANEL DISCUSSION

DR. HAGAN: So the blue ribbon panel that the VA assembled did several separate activities that were really very helpful. But one of those was to point out that within the literature, no one had really examined other than some attention given to a rectal dose associated with prostate implant what

reasonable constraints there would be on the quality of an implant if one examined the dose to the rectum, dose to the bladder, dose to periprostatic soft tissue.

But, at the same time, there was an active protocol going forward where physicians consulting for the American College of Radiology had identified at least at that point 400 prostate brachytherapy implants as being gold standard implants; that is, valid in every aspect required by the phase 3 protocol that was ongoing.

And this protocol came on the heels of effort between RTOG to identify in a systematic way the ability to be able to do prostate brachytherapy protocols. So it is the first. It is not quite closed out yet, but that protocol will probably be closed out this year and so the meeting is successful, accrual goals.

So that gave us a database that existed that could speak to dose to other organs and tissues. And so the ATC WASU directed by Jeff Michalski worked with RTOG, the Radiation Therapy Oncology Group of the ACR, the stat section, to review these implants and determined what dose the rectum and bladder and non-otherwise described periprostatic soft tissues

around the prostate were receiving from well-done implants. And that data actually is the subject of an oral presentation, I believe, at the next ASTRO meeting and will be published this year.

The evaluation results were published as an appendix to a paper that I wrote with Jeff Williamson that came out in Brachytherapy that was the reevaluation of the Philadelphia implants using image correction. But with that, there is an appendix. And the appendix is this blue ribbon panel's report. It includes these observations.

The observations actually solidified what we intuitively felt. That is, intuitively, the dose outside the planted target volume immediately adjacent to the planted target volume should be one would expect very close to the prescription dose. And, as you move away from that target volume, the dose should fall off precipitously.

So if we looked at the highest dose that the immediately adjacent rectum or the closest bladder subvolume or the periprostatic tissue immediately adjacent to the target and looked at the highest dose to a very small volume, that dose ought to be very close to the prescription dose. And that was indeed the finding.

It was not quite exactly the case. I think the highest dose to one cc of bladder for -- with a confidence interval of 95 percent was about 93 percent of the prescription dose. And the immediately adjacent rectum was a little above 95 percent.

And so this allowed us to assemble data, which validated the opinion of the highest dose that should be tolerated by these treatments based on a well-done prescription. And then you could apply the regulation.

The regulation, which I showed in one of the earlier slides, requires you to report as a medical event a case where other organs and tissues are dosed to greater than 50 percent more than the expected dose. So if the expected dose to the hottest volume is approximately the prescription dose, then you should report as a medical event an implant which delivers to that same small volume a dose that's 150 percent of the prescription dose.

And that was the recommendation of the blue ribbon panel to the Under Secretary, so not based just on intuition of what you think would be correct but actually vetted by looking at cases from the RTOG.

That analysis was done in two steps. One was to identify the limits of these doses and then to

set a set of criteria and then to go back into that data set and pull an additional data set to validate the criteria. And both showed the well-done implants had really very narrow constraints on the doses.

Absorbed dose works here because we're away from any one seed's contribution. So absorbed dose does very nicely outside of the immediate target site. And this was a finding of this evaluation.

FACILITATOR SALTER: Okay. Dr. Ennis, would you like to make a comment? If I forget to introduce you before you make your comment, I would just ask that you do that for the folks on the webinar so they know who is speaking. So Dr. Ennis?

DR. ENNIS: Sure. So, I mean, I think those are interesting findings, but I do have some concerns or questions about them. A) I think the purpose here is not to define what a high-quality implant is, which those guidelines may be more relevant to, as opposed to what is an egregious event that needs to be reported to the NRC and to your hospital board, et cetera. I think those are very different criteria and very different endpoints and play different roles.

Number two, what we're looking for are doses or activities that are correlated with very poor

outcomes. And that is not what we have. We just have what good implants kind of look like, as opposed to what a terrible implant looks like.

So it's not really getting at while there may be the consensus of experts and we may need to rely on that definition that was more tightly correlated with a true what we're looking for might be better.

I do think this is 20 percent of your activity outside. That's egregious. I think everyone here agrees with that. And that makes sense as a definition for now.

We get more intelligence. We get more information. We learn more from the science of brachytherapy. We think we could move into definitions that are based on data. But I would caution developing definitions that are based on opinions of experts, as opposed to real data.

DR. HAGAN: Let me respond to that.

FACILITATOR SALTER: Okay. That's Dr. Hagan.

DR. HAGAN: Yes. So the rule asks for you to report based on the expected dose. So the issue was we have no reason to understand what the expected dose was. So what is the expected dose?

So the expected dose is based on your planned or the authorized user's planned implant. And so if you plan an implant and then you're also planning the dose to neighboring tissues as well by default and because this has not been looked at before, so the question is, what are the expected doses? So using a 95 percent confidence limit on the upper dose to these non-target tissues gave us an evaluation of the expected dose.

I absolutely agree that then the question is, how do you use that data? And what you are trying to do is to find the egregious violation. The rule currently says you want to be within 50 percent, 150 percent of your expected dose. So you can't be 50 percent greater than your expected dose.

So what this effort did was to define the expected dose for a prostate and those tissues relative to the prostate, but the rule is what determines when it becomes reported, meets a reporting requirement, and the current rule is 150 percent.

And you could easily argue that that rule is inappropriate for prostate brachytherapy. My guess is that's a rule determined by a committee somewhere and it may apply to one procedure and not apply well to another procedure. And 150 percent of the

prescription dose has no real clinical relevance in terms of outcome for prostate brachytherapy. I couldn't agree more with that.

FACILITATOR SALTER: Dr. Zelac had a comment.

DR. ZELAC: The fact that we need to as regulators look at basically two things in this procedure, one, was the physician able to accomplish what he or she intended.

And I think that primarily relates to the treatment site. And if you wish to do it in terms of source strength implanted, that sounds reasonable. I don't think there's any question about that.

The other question that also relates is the dose to the other organs or tissues, organs at risk, which is clearly part of what has to be considered in medical practice anyway. And the point is how far from what had been intended should be considered still acceptable, not necessarily resulting in harm to the patient but indicative of something about the procedures and protocols that requires at least a look, if not a correction.

So having some concern about other tissues and organs seems to be an appropriate thing for the regulation to address, but the question is, at what

level? And because clearly we not only have the immediate organs at risk that have been considered by the physicians presumably during the planning of the treatment or in the conduct of the treatment but also the question that Dr. Welsh brought up before about tissues that are at a distance that are receiving low doses and this criterion or some criterion also possibly applying to them as well.

So it's really two issues I think that need to be considered. One is, do we have a need, as some people will say, to have consideration of the doses to doses, not activity implanted but actual doses, absorbed doses, to other tissues and organs and at what level? And, two, how do we handle more distant organs, where, as Dr. Welsh had pointed out, the doses are low? And doubling as an example, expected dose is not going to have any clinical significance on the outcome for the patient.

FACILITATOR SALTER: Dr. Ennis, did you want to respond?

DR. ENNIS: So, I mean, I do think that in some ideal fashion, using dose would be sensible. It would have to be very tissue and organ-specific. We just don't have that knowledge to make some intelligent comment about what volume of bladder, what

volume of rectum ought to get a particular dose, which would be defined as an egregious event.

I think, you know, for better, for worse, the best we can do with 20 percent of your seeds or your activity is outside and in those other tissues. That's a very big problem. And that should be a medical event. I don't see us being able to be more sophisticated than that at this time.

In terms of the low dose to the surrounding organs, it is inconsequential. I don't know how we define that. I think just dropping that whole issue. I mean, five centigray to the femoral heads, I mean, it's completely meaningless. And if you double that to ten centigray, it's still completely clinically meaningless.

FACILITATOR SALTER: Dr. Welsh? And I would just remind the panelists to speak into the microphone so that the folks on the webinar can hear.

DR. WELSH: I would agree with what Dr. Ennis has just said about the need for either dropping the present definition or improving it so that it is more meaningful and relevant to general genuine clinical practice.

I'll read what the present part 35.3045(a)(3) states as a medical event, "The dose to

the skin" -- and keep in mind the skin is something that we really don't keep track of very carefully or have any reason to for prostate brachytherapy -- "the skin or an organ or tissue other than the treatment site that exceeds by 50 rem" -- and, again, 50 rem is a tiny dose when we are talking about giving 150 gray as a prescription for the prostate -- "to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the written directive excluding for permanent implant seeds that have migrated from the correct site subsequently."

So, keeping in mind that 50 rem is a very tiny dose and it may be meaningless, 50 percent could be medically inconsequential if we're talking about tiny doses in the first place, and that hopefully we will be able to acquire some data -- as Dr. Hagan has pointed out, maybe some of this data will be presented at ASTRO this year -- that will allow us in the medical community and NRC as regulators, if necessary, to even include comment or regulation about normal tissue doses that at least the figures make some sense, that they are more appropriate than the current language indicates.

And an important point that needs to be kept in mind is that 50 percent or 50 rem, as

presently stated, without a volume or area is relatively meaningless because with prostate brachytherapy, the amount of radiation in the area adjacent to a seed can be quite high. And if you are talking about point doses, exceeding by 50 percent or 50 rem is quite possible, yet medically inconsequential.

So if something of this sort needs to remain, it would be strongly recommended that it be accompanied by a specified volume or area, rather than the presently ambiguous point doses.

FACILITATOR SALTER: Dr. Mower?

DR. MOWER: I'm looking at the fact sheet that was handed out this morning from the Nuclear Regulatory Commission. I would like to ask possibly Dr. Zelac or some of the others here to comment on a couple of the statements that are in here relative to what is a medical event.

The licensee had technical or quality assurance problems -- I'm not sure most of what we're seeing here would fall under that -- that it resulted in an error. Was it an error over what the doctor intended to do and that it indicates a potential problem in the medical facility's use of radioactive materials?

Those are the things which the NRC has labeled as part of a medical event. And I'm not sure that in any of the things that we are looking at here relative to a couple of millimeters, what the volume is that we're talking about, how we prescribe the dose, when we should prescribe the activity relative to the implant would fall under this outline of what is considered to be a medical event.

FACILITATOR SALTER: Dr. Zelac?

DR. ZELAC: The main purpose from my perspective in having medical events as reportable is to bring to light situations where the physician had an intent and that intent was not achieved. There was a variance of the result from what the plan or the intention had been.

Now, I think we go from there down to the details of how you define that, but I think that is the starting point. And I think it applies to the kinds of things that are in that statement, although I didn't write it and I haven't looked at it ever.

(Laughter.)

FACILITATOR SALTER: Dr. Mower?

DR. MOWER: I guess a part of that, then, would go back to, though, when is the official intent decided upon? When the surgeon goes to operate, is

the intent what they see before they open the body and look inside to see what is sitting there or is it when they open the body and see what is there? Is the intent in prostate brachytherapy when the physician first sees the patient three months earlier or four months earlier or is it what the prostate looks like and what the disease status is and the size of the prostate on the day of the procedure?

FACILITATOR SALTER: Dr. Zelac?

DR. ZELAC: Even with the current rule, which we are attempting to improve, it is possible for the physician to make the determination of what that intent should be at the very last second before the implant begins based on what is observed with the imaging that is available, what is observed with all aspects of the procedure, including the condition of the patient.

FACILITATOR SALTER: Dr. Welsh?

DR. WELSH: I might just simply reply to Dr. Zelac's point by saying that sometimes things do change during the procedure that can influence the clinician's actions so that they might even differ from what the intent was at the time the implant was planted right before the procedure begins.

Once you place the first seed or two or

needle or two in, things can change. Prostate brachytherapy is actually a dynamic procedure. And I think, as Dr. Mower was alluding to, the surgeon who has opened the patient is encountering a dynamic situation. And things can change on the fly. And things can change on the fly in prostate brachytherapy, perhaps not to the same extent, but there is a definite amount of clinical judgment or art, if you will, to this science.

FACILITATOR SALTER: Dr. Zelac?

DR. ZELAC: That's exactly why we're looking at the rule now, because the rule as it stands doesn't take into account exactly what you're pointing out. The fact that there is a dynamic situation and decisions are being made on the spot is something that the current rule just cannot consider in its dose-based form.

If we move to an implanted total source strength for the treatment site itself, I think we'll overcome most of that, particularly if that statement from what the total source strength implanted is is made at the end of the procedure.

So that there should still be medical events, even with that in time entry into the written directive, but it would be based on, for example, the

wrong radioisotope being used or wrong source strength being implanted, not on the resultant dose.

FACILITATOR SALTER: Dr. Ennis, did you want to --

DR. ENNIS: Just I think those are very good comments. As long as the physician could at the end of the procedure be able to modify or amend the pre-op directive to say "I have purposely implanted more activity on the left side outside of the prostate because of what happened during the procedure. And that would be kind of now considered his intent." And then that is considered, you know. And then anything over and above that would be an issue.

I think that would make perfect sense because, as Dr. Welsh mentioned, imaging changes can happen. You can note edema. You can note both the quality of the imaging can deteriorate. And you then have to make a judgment. You may purposely put some seeds beyond the prostate, beyond your PTV, with intent for the patient's best interest to make sure you do a quality implant and control as cancer.

You need to be able to define at the end to the procedure what your real intent was.

FACILITATOR SALTER: Let me go to Maureen Eisner, our patient advocate representative on the

panel, and ask if you would like to make any comment on this particular issue or something else you heard this morning.

MS. EISNER: Yes. Actually, I would like to comment on one of the panelists' comments about the fear of liability and certainly negative implication of medical events. And I realize that that is an issue. I think that it is repeatedly coming up.

If there is no harm to the patient, there is no liability. And I think the implications and the stigma that is attached to the medical event -- and I don't know if this is possible. Perhaps there could be different categories of medical events, one that causes patient harm, one that does not cause patient harm but has potential to cause patient harm, and maybe a third that has -- it wasn't the intent of the physician originally but can be looked at, certainly for future care of the patient or other patients, so that there is not the stigma.

The other part of it is the consent piece. I think, again, one of the panelists had commented how the patient may feel that the physician has not done a good or reasonable job at this. I think if patients have an understanding of how much that this is not an exact science and it has to be looked at, even

actually while you are doing the procedure, that the more the patients have this understanding, it wouldn't have the stigma that is attached to it. I think that patients need to know that anyway as well. So perhaps it might impact on some of these other issues.

FACILITATOR SALTER: Dr. Welsh?

DR. WELSH: Thank you. I appreciate the opportunity to speak to some of those comments. They are very important.

I would agree 100 percent that there probably should be varying levels of definitions of events, but presently the term "medical event" does indeed have a very serious negative connotation and does have an impact on what happens subsequently, not necessarily medically but legally.

I would love to see things other than medical events defined, such as maybe minor violation. And the post-implant dosimetry being done after 60 days could be a violation but certainly wouldn't qualify in my opinion as a medical event, even though we all agree that it should be done and regulators need to have a time frame, therefore.

The topic of medical event typically is discussed in the informed consent procedure. And that is standard practice for many of those who practice

prostate brachytherapy, probably not all. It certainly is a good idea because the patient can, therefore, understand that there is this category of regulatory policy wherein if seeds are slightly different from what the physician intends, it could be of no medical consequence, but it could be a regulatory violation. And, therefore, you could some day be informed that your procedure, while still medically appropriate, unlikely to cause harm to you as a patient, still likely to cure you of the cancer, may be termed a "medical event" for medical legal reasons.

The truth is that when that happens, I think all who practice radiation medicine, particularly brachytherapy, are aware that patients, even if they do understand, will often wind up perhaps victims of the legal environment.

And I have known many situations wherein an attorney has been consulted and retainer paid and investigation initiated for no justification whatsoever and no true medical or legal grounds to proceed. But it seems to me that it is an unfortunate reality that such events do occur and that patient winds up losing twice because of the anxiety associated with the terminology "medical event" and

the anxiety and cost of pursuing the legal avenue. And perhaps if this legal avenue were not so likely to be pursued, we wouldn't have this conversation, but the fact is that anybody who practices medicine, particularly brachytherapy, is likely to know exactly what I am talking about.

FACILITATOR SALTER: Can we go back to Ms. Eisner to respond to that? And then we'll go to Dr. Ennis and Dr. Zelac.

MS. EISNER: Just to respond quickly, I think that's more a matter of legal ethics. And if there is really not any basis legally for the lawyer to take on a case, it would be very difficult, it not impossible, for that lawyer to win that case.

So it is a shame that it is even coming into this discussion because, really, it should be about doing obviously what is best for the patient and not limiting that by some cruel defense of medicine but certainly not limiting how we are treating patients because of that fear.

FACILITATOR SALTER: Dr. Ennis?

DR. ENNIS: So aside from the suit issue, though, it needs to be understood that a medical event can have and often does have profound effects within the physician's practice and hospital environment,

something declared a medical event as viewed by the president of the hospital, the QI community of the hospital as a very serious event. And this can have very significant effects on the physician's ability to practice.

And, again, if it's not a justified event, if the physician actually did what was in the patient's best interest but that his practice suffers, his privileges are denied. Insurance company may declare him no longer fit because he's had a medical event.

These things are real things that happen to real physicians in the real world across the country. So we need to be very careful that we don't hurt people in some noble goal but hurt well-meaning physicians and their potential patients in the future through regulations that aren't based on the current reality.

FACILITATOR SALTER: Dr. Zelac?

DR. ZELAC: Just to add a few things to what has been said on this topic already. First, a medical event is not a violation of a regulation. It is an attempt to bring to light information about protocols and procedures that may need looking at, not necessarily a change but at least looking at, because

the results didn't agree with what the physician had intended.

Secondly, I think it's worth looking historically at how we got to where we with a term "medical event." There used to be in the regulations a term "misadministrations." And it was the response of the general community to that term which led to being changed to something which was hopefully more acceptable and not so onerous in terms of its implications.

Apparently we're not there yet. And I would be certainly open for any suggestions from anyone at any time as to what we might call this class of events other than medical event to identify what it is but not have the connotations that apparently even our current term does.

FACILITATOR SALTER: Dr. Hagan?

DR. HAGAN: Yes. I think an issue is not so much what we call it but how we treat it. And if you want a medical event as an entity to be able to capture what are essentially near miss events; that is, issues where the practice has deviated but have no clinical consequence, and at the same time that same entity to cover those egregious errors, which obviously require disclosure, disclosure to the

patient, disclosure to the referring physician, I think you're fighting a losing battle because you have too large of a spectrum of event consequences that you are trying to fit into a single definition, a single label.

I think one needs to separate those actions and create entities that are appropriate for each.

FACILITATOR SALTER: Dr. Welsh?

DR. WELSH: I would agree with what Dr. Hagan has just stated. And, in response to what Dr. Zelac has pointed out earlier about the term "misadministration," we all know what the word "misadministration" has obvious negative connotations. But now we all know that that term no longer exists and has simply been replaced by the synonym "medical event."

So to replace a word that has clear negative connotations with another term that sounds friendlier but is exactly synonymous leaves us in the same situation, which is why Dr. Hagan's point about perhaps having varying levels would be appropriate.

The egregious medical event or misadministration may be appropriately called something with a serious name. Something that is a

near miss that identifies trends that could lead to problems down the road perhaps should not be categorized in the same group with the same term.

FACILITATOR SALTER: Dr. Ennis?

DR. ENNIS: So I guess it is a question. One is a question and a comment. The question is, from the NRC's perspective, the other events that we are talking about are more of medical QI events. And in our department, we have a whole QI procedure and process where we look at these types of things.

And does the NRC view itself as a regulator or decision-maker about QI, medical QI, processes -- and perhaps they do -- or are they really only wanting to protect the public from severe radiation potential events or severe radiation misadministrations, to use that other term?

I kind of thought we were talking more of the former. The other levels that we are discussing here, which are a good idea and many institutions probably do them, could be incorporated in NRC for sure if that were law. And I would support certainly the idea of people evaluating those as QI indicators and measures.

We would need to be concerned about protection of that information. Members of ASTRO

certainly would be very concerned about how that information is handled and who has access to it and under what circumstances.

But done appropriately as a QI tool, it could certainly be done, although I do think that it is more of the purview of the individual practices and hospitals than the NRC.

FACILITATOR SALTER: Dr. Zelac?

DR. ZELAC: I will speak from what I believe the position of NRC is. And I will be ready to stand corrected by anyone from the agency who thinks differently. But NRC does not want to be the regulator to whom events are reported that are harmful to the patient. That's too late.

They want to know about these events, certainly. And those types of events need to be reported, certainly. But by the time that occurs, we're too far down the road.

And that's the reason for looking at events, near misses, so that we don't get to the point where there are patients that are actually harmed, as compared to other agencies, which will remain nameless, for which that is the criterion for reporting. If the patient is harmed, you must report. But near misses don't get reported.

We think in the interest of our obligation for protection of the public, that these near misses should come to our attention not as violations but as clear flags that something at the facility, with the procedures, perhaps with the particular authorized user, needs to be looked at very carefully so that we don't get to the situation where there has, in fact, been actual harm to a particular patient.

FACILITATOR SALTER: Ms. Eisner?

MS. EISNER: And, of course, I am in full agreement with that. I think that anything that overall is for the greater good certainly, you know, should be looked at and analyzed.

And, again, I don't know if it's possible even to have these categories as far as near misses and things that can be looked at. So maybe, again, the stigma isn't there as great, but I think it's very, very important that we try to prevent harm to the patient.

FACILITATOR SALTER: I would just remind the panel that this is your opportunity to bring up whatever issues, make whatever comments you would like, but if -- oh, there we go. Dr. Mower?

DR. MOWER: If we are going to do a major change and shift and whatnot, I would like to go back

to the survey that was sent out by the Organization of Agreement States. It was commented that no state mentioned the concept of activity-based reporting.

Was this listed as an actual question on the survey or was that something that could have been put in as a comment? Because we all know if a question is there, you will get more responses than if you kind of leave it up to people to sort of think about something else.

MR. DANSEREAU: I can answer that.

FACILITATOR SALTER: Robert Dansereau?

MR. DANSEREAU: That was the last question on the survey. And it was for the states to make any comment in the area regarding the medical event criteria. It was just a comment that I had that no one had made a comment about activity-based. It was not a question.

I think the survey was good, but in answering questions, it raised more questions.

FACILITATOR SALTER: Dr. Hagan?

DR. HAGAN: I think it is worthwhile to note that among the panelists in their original presentations and comments thereafter, unless I am missing something, there seems to be a good consensus on the use of a source strength-based metric for

determination of dose to the target tissue.

FACILITATOR SALTER: Anyone want to comment on that? Dr. Welsh?

DR. WELSH: I'll just follow up with a couple of points. The Medical Event Subcommittee of the ACMUI conducted their annual exercise and found that prostate brachytherapy, which was plagued with this inappropriate definition of medical events that is the subject of today's workshop, has led to what I believe is about tenfold increased incidence of reporting of medical events compared to what the baseline truly could be.

I would be hard pressed to present actual data to confirm that. I know that the question has been posed of the VA series, for example, what fraction would truly be medical events if we used a more appropriate definition. But I can say that the baseline of medical events in permanent implant brachytherapy, manual brachytherapy is about 0.03 percent; whereas, in permanent implant brachytherapy, it has been approximately 0.3 percent, tenfold higher.

So I personally believe that this is a consequence of the inappropriate definition that we hope to correct, but I did hear in a presentation today that in, I think it was the State of Wisconsin,

my former home state, that the incidence of medical events with prostate brachytherapy is just under three percent and, therefore, not terribly inappropriate.

I have to strongly disagree with that. As anybody who practices prostate brachytherapy on a regular basis, probably does 100 cases a year or so or maybe many more. If every year there were three medical events, that person might become loathe to continue practicing prostate brachytherapy because, as we have heard, as much as we don't want this to be the case, the fact is that medical events are serious for hospital administration, for patients, and they have an impact on the physician. Maybe that wasn't the intent of the term "medical event," but that is the reality.

And, therefore, three percent is far, far higher than it should be. 0.3 percent is probably too high. And if we could get to a definition that truly is appropriate, I suspect that prostate brachytherapy, which in my estimation is an effective and safe treatment, will have a medical event rate of approximately 0.03 percent. And that would be something that I hope we can attain through appropriate definition.

FACILITATOR SALTER: Ms. Eisner?

MS. EISNER: I'm going to comment. And I think the fact that the number of medical events, the number is going up, I don't know necessarily that is a bad thing. And you are looking at ways in which overall you could help improve the treatment. And maybe I am misunderstanding, but I think that is what you are saying, that these numbers are going up.

I think we are looking at it as -- and excuse me for saying this -- on how it is impacting on the physician. But I think, really, the focus needs to be looked at as how it's impacting on the patient and whether or not it is helping.

If it is truly not helping the patient going forward, then I don't see any purpose for it. But if it is helping in analyzing how the patient should be treated and, again, near misses and things that might be looked at before the patient is actually harmed, then I don't see it as necessarily a bad thing.

FACILITATOR SALTER: Dr. Ennis, would you like to comment?

DR. ENNIS: So, I mean, I think what you have heard as the thrust of the presentations show that the definition that is being required to be reported are irrelevant to the patient's outcome, the

patient's care.

They don't correlate at all with successful cancer cure or complication rates. They are an arbitrary definition that when applied rigidly -- and the reason for the increase is people are starting to apply it rigidly. It's not that the implants are changing in quality. It's just that the rule is being applied more rigidly. And suddenly people are saying, "Oh, my. This is considered a medical event."

Now, I have dozens of patients who were treated this way in the past. And they are doing great. They're cured of the cancer. They're potent. They have continence.

So the problem is not that we're trying to not learn and not improve. The problem is that the definition is very onerous in its implications and is irrelevant to patient outcome. It does not correlate with any important patient outcome.

FACILITATOR SALTER: Dr. Mower? And then we'll go to Dr. Welsh.

DR. MOWER: I'm probably the wrong person to comment on this since I tend to be a physicist and work more with physical-type things and whatnot. And it was alluded to earlier by one of the speakers the

current usage of medical event when one starts talking to the patient, there may not be a physical problem, but what is this doing to their psyche and their psychological outlook on things?

And are we creating more problems there for the patient and the patient's well-being than we really need to under the guise of saying that we're looking for something else? And possibly one of the clinicians could respond to that.

FACILITATOR SALTER: Dr. Welsh?

DR. WELSH: I think I am going to just say exactly what you just stated in other words. But, to reply first to Ms. Eisner's important point that the patients need to be aware of anything that could impact their health, their chances of cure, their chances of side effects, it is critically important that we always keep the patient first.

And I do believe -- I could be wrong, but I do believe that most practitioners of brachytherapy do keep that in mind. The patient comes first.

Having said that, the current definition of medical event is such that, as Dr. Ennis has just stated, many procedures that are perfectly acceptable medically are inappropriately titled "medical events." And, therefore, many clinicians routinely say, "If

it's a medical event, my patients have to be aware of that because I don't want them finding out from a state regulator or the Nuclear Regulatory Commission that a medical event has occurred. I want them to hear it from my own mouth that this was a medical event and explain what that truly means in terms of its significance," maybe nothing in terms of medical significance, but the conversation provokes a great deal of patient anxiety.

As I think you can appreciate as a patient advocate and any physician who has had to participate in this, that can be a very uncomfortable experience for the patient to let the patient understand that this is a medical event, there may be a lot of paperwork, there may be individuals contacting from the state and others, and that in the end, it has no medical consequence.

Sometimes patients will become anxious and start to wonder about the validity of what the physician is saying if there is inconsistency between what the physician is saying about medical consequence and what the state or the Nuclear Regulatory Commission is saying about this being a deviation from physician intent and, therefore, being titled "medical event."

So the patient anxiety factor is something that always needs to be considered. And, therefore, it's another justification for making sure that we get the definition right for all parties involved.

FACILITATOR SALTER: Ms. Eisner?

MS. EISNER: And I agree with you, Dr. Welsh. Certainly we don't want to give patients anxiety. However, if there wasn't any harm done to the patient and the patient understands it is for the greater well-being of all patients that these things be looked at, I think most patients have the sophistication to understand that.

And mixed messages should never be sent. I agree with you. And I think if other people are contacting them, certainly that should be explained in the same way.

I think, again, defining it in different categories might be something that might be helpful to the patient. But if the information is helpful overall, it should be looked at. And, again, like I said before, if it's not, then that is something else that should be analyzed.

Thank you.

FACILITATOR SALTER: Again, this is your opportunity. Dr. Zelac?

DR. ZELAC: Because we as the regulators have to take all of this information and do something with it in terms of actually putting something down on paper that will be both useable for us and liveable for the physicians.

I would like to revert to some of the questions that were in the Federal Register notice that we wanted answers for if possible or at least input on from the various groups represented here.

They're not, as I might ask them, phrased exactly the same as in the Federal Register notice but close enough that I think we'll get to where we want to go. And, by the way, the fact that I am asking these questions now of the panelists certainly is not to preclude input from others in the audience this afternoon, either in the way of a comment on what you hear or an opposing statement perhaps.

The first one, should the medical event regulations have a specific section for prostate brachytherapy, rather than being combined with all other permanent implant brachytherapy?

And we have heard from the AAPM, but I would like to hear from others as well. Should there be separate regulations for prostate?

FACILITATOR SALTER: Dr. Ennis?

DR. ENNIS: So I think that not necessarily -- there are two situations, it seems to me, where separate regulations may, although difficult, be needed. One is when the tissues are manipulated after the seeds have been implanted.

And in certain types of situations, not prostate but lung is a good example. But there are head and neck implants as well where permanent seeds may be put in the location.

And then the surgeon then goes ahead and completes the surgical closure, perhaps do a transplant of tissue, a graft, et cetera, that could displace the seeds. Again, it's become somewhat out of the user's control.

So a regulation that deals with that uncertainty and that variability needs to exist separate from prostate and potentially others, where there is no further manipulation of tissue where that class I think could have a similar regulation.

DR. ZELAC: This is Dr. Zelac. So what you're saying, then, is that the 20 percent of source strength within the treatment site or outside of the treatment site would not be an appropriate criterion for whatever you want to call the report for those types of treatments. Is that correct?

DR. ENNIS: There might need to be some modification of that to allow for the fact that surgical manipulation has caused this to occur.

DR. ZELAC: Okay.

FACILITATOR SALTER: Anyone else want to comment on the combining prostate implant brachytherapy with all other permanent implant brachytherapy? Dr. Welsh?

DR. WELSH: So while I and the ACMUI subcommittee don't have very strong feelings on this particular matter, I think that we perhaps are slightly differing from Dr. Mower and the AAPM's perspective simply because of what Dr. Ennis has said about rearrangement of seeds during completion of the procedure, during certain brachytherapy procedures. Head and neck was a good example. Lung brachytherapy is another example wherein seeds can wind up in a very different location on subsequent follow-up CTs compared to what they might have looked like in the operating room.

Prostate brachytherapy, on the other hand, is fraught with its own challenges, as we have discussed many times about anatomical size and shape changes following the implant, challenges with contouring the prostate itself.

And, therefore, the ACMUI subcommittee at one time advocated two separate categories: one for procedures in which there was significant rearrangement or at least potential for significant rearrangement upon completion of the surgical implant procedure and those where this is not the case but does have a separate potential problem, such as edema and atrophy.

What this really amounts to is non-prostate and prostate. But, having said this, I don't think that there was a strong feeling on the part of the ACMUI and the subcommittee for separating the two. If an appropriate definition could encompass all, it would be great, but at the time this subject was being debated, we were having some challenges coming up with some of the definitions. And certainly the re-proposed rule made it difficult to not categorize things in separate fashion.

So at this point if we come up with a rule that will work, maybe there is no reason for prostate versus non-prostate.

FACILITATOR SALTER: Anyone else?

(No response.)

FACILITATOR SALTER: I think one of the panelists had touched on the imaging modality, when

and what type of imaging modality, to verify seed placement. And I believe we had a question in the Federal Register on that. Would anyone like to make a comment on that? Dr. Ennis?

DR. ENNIS: Well, defining a specific time I think would be problematic because currently it is a tremendous debate within the community about what is the proper time.

Some of it does depend on the seed that is used because of the varying half-lives. But there really is not a consensus because there is just not an answer to that question. It depends on edema of the patient, et cetera, that you can't even predict.

Some outside number. I could see why the regulators would want some outside number to make sure it gets done. And that would be potentially reasonable.

Again, to declare, as Dr. Welsh had said before, it an actual medical event, if it's not done, particularly if it's due to the patient's noncompliance or travel, et cetera, and these are the realities of life, that ought not be a medical event, but some level of requiring some outside level, 60-90 days I think would be reasonable, beyond that, to try and regulate that and what type of imaging to be done.

Again, everybody pretty much uses CT right now. That is clearly suboptimal. There is research going on into newer modalities, but, you know, we are not there yet in terms of being able to incorporate that into a regulatory environment.

FACILITATOR SALTER: Dr. Welsh?

DR. WELSH: I might just follow up with mentioning that, as Dr. Hagan's slides illustrated, there is a huge discrepancy or difficulty that is naturally encountered when comparing ultrasound to CT.

Ultrasound often allows us to identify the prostate during the inter-operative stage of the procedure with a reasonable degree of certainty and accuracy. CT, as we all know, does not have the same level of certainty and accuracy.

And, therefore, we're putting the seeds in under ultrasound guidance and then estimating the post-implant dosimetry based on CT, the CT modality. And that is an inherent challenge because we're going from one modality to another, in addition to all of the anatomic changes that are occurring in terms of volume, size, and shape, which is the possibility that you could have the prostate defined by one user in the operating room and a different user during the post-implant dosimetry.

You have inter-observer differences as well as inter-modality differences, which, as we all know, there are intra-observer differences. So these are just being magnified one after another after another, which underscores again the point where volume-based metrics really are inappropriate and hopefully will come to an understanding with something that is more source strength.

FACILITATOR SALTER: I just want to remind the panel that we're not trying to limit you to these questions, but if there is no other comment, I will defer to Ron if he has another question that he wants to ask. Dr. Zelac?

DR. ZELAC: Let me just point out on the one that we have been discussing now, first, if the patient doesn't show up, for whatever reason, it clearly is not going to be a medical event, period. That's patient involvement, patient intervention that prevented, precluded a physician from doing what had been intended. So that should kind of be taken off the table.

In terms of the criterion that I think we are starting to focus in on, the amount, the total source strength implanted within the treatment site itself and variances from that, 20 percent outside of

the treatment site, when should that determination be made? Should it be made promptly after the procedure is "completed," the implantation is done, or should there be a waiting period for when imaging is going to be done for dosimetric purposes later?

FACILITATOR SALTER: Dr. Ennis?

DR. ENNIS: I would see no reason to just not to just use the dosimetric imaging that's planned to be done at a later time. In terms of what we are now kind of talking about as a definition of the high percentage of seeds outside of the prostate, they are going to remain there. You don't have to look at day one to see that they're going to be there and just using one CT scan.

We don't really want people to have two CT scans and all the implications have two CT scans and cost to the health care system, radiation exposure to the patients, et cetera, that's unnecessary. I don't think it would be wise to require two sets of scans. And I don't think it would interfere with the application of the definition that we're discussing.

FACILITATOR SALTER: Okay. Dr. Welsh?

DR. WELSH: I might just add that I think most practitioners, certainly the ACMUI, I suspect ASTRO and everybody else, agrees that post-implant

dosimetry is an important component of a prostate brachytherapy program. And it really should be done. Many society recommendations have stated this clearly.

However, it becomes tricky in terms of the regulatory aspects of it. Just as D90 is used for reporting in the medical literature but is not appropriate for regulation, I have to wonder about a time frame for post-implant dosimetry, which is perfectly reasonable in the clinical world but becomes fraught with challenges in the regulatory world.

And although a 60-day imposition might make sense from a medical perspective, I would caution that it could lead to some difficulties in the regulatory world, ignoring for a moment the patient who doesn't show up at all. But what about the person who shows up on day 61 because of a simple oversight clerically? Is that going to be a medical event? I would submit that it probably should not be. So I think that there could be a lot of difficulties.

I appreciate the converse that the NRC must face wherein they say that if post-implant dosimetry is necessary, you can't say that without having some kind of timeline because you could catch somebody who has not done the post-implant dosimetry and they just say, "Oh, we typically do it at two

years post-implant" or something and get away with it.

As unlikely as that might be, it does illustrate that having some kind of timeline is probably appreciated by regulators and, therefore, ACMUI is flexible on this. But 60 days is a controversial point at this moment.

I would love to see what others feel about this.

FACILITATOR SALTER: Dr. Zelac?

DR. ZELAC: All morning long we have been hearing about activity implantation into the treatment site. And when there is variance from what had been intended, when a fraction of that is planted elsewhere, that that should be brought to the attention, whether we call it a medical event or something else.

The question I would ask, however, is, is 20 percent the appropriate number? Should it be something else?

FACILITATOR SALTER: Dr. Ennis?

DR. ENNIS: Well, we had no basis for deciding any percentage, obviously. As I have been arguing about the dose, we don't have any evidence that 20 percent is bad either. But I do sense a strong consensus among practitioners and members of

this panel and other people that that is egregious enough that any expert or any reasonable practitioner who is practicing would look at that type of implant, say, "This is terrible. This is clearly an inappropriate application of radiation."

At least for a starting point or a point to move forward from this seems to be a consensus in our community at least that that is a definition that practitioners agree is a misapplication of radiation to a significant degree.

FACILITATOR SALTER: Dr. Welsh?

DR. WELSH: I might add that I agree that we don't have scientific solid data to say 20 percent is the absolutely appropriate number. But I think most of us, using a little common sense and judgment, agree that 20 percent is quite reasonable.

There could be a regulatory challenge that might be encountered when practitioners use variant B in Dr. Hagan's presentation. Variant A was with all the seeds within the prostate. Variant B was where the practitioner chooses to put some in extra-prostatic location.

And both of them work very well. Both of them have equivalent clinical outcomes in terms of cure and side effects, but here is where the

terminology that has traditionally been used becomes a little bit too vague when we talk about the target site.

And here is where I think that it might be appropriate to use modern terminology, such as gross tumor volume, clinical target volume, and planting target volume.

And in Dr. Hagan's slides, both practitioners have the seeds within the planning target volume. And both were done appropriately in accordance to what the authorized user wanted to do. But it could be very difficult for a regulator who is not fluid in this particular subspecialty to not label the second approach where the seeds are outside the prostate as a medical event unless we have a tighter definition for target volume.

FACILITATOR SALTER: Dr. Ennis? And then Dr. Hagan.

DR. ENNIS: I'm glad you brought it up because I was assuming we were talking about planting target volume. So that means what I intended to implant. And that is purposefully not the prostate.

Very few people only implant the prostate itself for a lot of the reasons that we have discussed before. Most brachytherapists will purposely implant

at least a little bit, maybe a few millimeters, some even more than that, beyond the prostate, with intention and with excellent outcomes. Some of the best outcomes are in centers who do this as a conscious thing.

So in terms of the correlation between the physician's intent and the outcome that NRC is looking to, it seems clear that we need to at the time of the written directive say, "Okay. This is what I'm planning to do to the planting target volume" and then measure that against the post-implant analysis.

FACILITATOR SALTER: Dr. Hagan?

DR. HAGAN: Just to add sort of some real world experience to the 20 percent number, when the blue ribbon panel looked at cases from the Philadelphia VA Medical Center, it was clear that there were implants that looked inappropriate. Without any quantitative eye, just examining the implant, the implant appeared to be inconsistent with an implant, the intent of which was to treat the prostate.

Now, they actually were very few in number. And when we looked at those that had 20 percent of activity outside of the planting target volume, out of 116 implants, there were 17. All of

the rest had on average 96 percent of the source strength material within the planting target volume. But there were 17 where that was not the case where 20 percent number was exceeded.

Out of those that clearly looked inappropriate to the panel, some of those that were at 20 percent really didn't bother the panel. Those that were 25, 35, even 40 percent were clearly inappropriate to even the untrained eye. And these very trained eyes picked up perhaps a dozen of the 17.

But, to make Dr. Ennis' point, these patients as a group are doing very well. And their incidence of these patients with 20 percent of seeds outside the planting target volume are doing very well. And their incidence of biochemical recurrence is very low and absolutely in keeping with the published literature.

So, even correlating 20 percent with a clinical outcome, you know, it's not going to happen. So we set a limit that's based on experience, but at the same time, we are well beyond the safety factor that would be built in in order to be able to demonstrate an implant that clearly has harmed the patient in terms of under-coverage.

FACILITATOR SALTER: Well, we are about

two minutes from 12:00 o'clock, which is our break time for lunch. I want to thank all of the panelists for everything this morning: your presentations, your dialogue. The panel members are asked to come back and sit at the head up here on the stage after lunch so that if someone wants clarification on something that one of the panelists said, they can ask it and they can respond.

In addition, you all will also be able to comment during the public comment period if there is something that you would like to bring up that you didn't have a chance to here during the facilitative dialogue.

So, with that, I just want to --

PARTICIPANT: Can we leave things in the room over the break?

FACILITATOR SALTER: Can we leave things in the room over the break? Can you go ask if they're going to lock the room and we can get an answer to that before we break?

And we are getting back at 1:30 for public comment. And so I would again remind you to fill out a blue card if you would like to make a comment.

And, to just kind of close up our morning session, I am going to ask Mike Fuller to come up and

let's have some closing remarks.

MR. FULLER: Thank you, Susan.

I would like to echo Susan's comments. We do really truly appreciate the comments and the discussion that we have had this morning.

I have one other announcement I would like to make. And this is good news for those of us who have been working on these workshops. I did get confirmation just before the last session that the Houston workshops are now up on the website. So folks can go to the meeting website and register for the Houston workshops now.

And I can verify that the location is going to be at the Marriott Texas Medical Center facility there on August 11th and 12th.

Now, we have sent out this link to our meetings website numerous times, but I don't think I have ever -- well, I will just go ahead and read it out for those of you who want to jot it down.

I think there may be a number of folks that are out on the webinar that are planning on attending the workshops in Houston. So maybe this will be useful.

Again, the website for our medical rulemaking workshops is

www.blsmeetings.net/nrcmedicalrulemakingworkshop. Again, www.blsmeetings.net/nrcmedicalrulemakingworkshop.

And, with that, I guess we will go ahead and break for lunch. Everybody be back around 1:30 or so. Wait a minute. Around 12:15, the room will be locked up. And then we'll open it up shortly before the 1:30 time that we are due to be back.

(Whereupon, a luncheon recess was taken at 12:01 p.m.)

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

(1:33 p.m.)

FACILITATOR SALTER: We are going to go ahead and get started with the second part of our presentation. So just a couple of quick reminders in case you weren't here this morning or in case you were, remind you to turn off your -- or put your electronic devices on the silent mode so that we don't interrupt the meeting. If you need to take a call, that's fine. We just ask that you go outside of the room to do that.

And also we want to remind everyone that we are transcribing this meeting. So if you can just keep the sidebar conversations down?

Again, you know, yelling comments out from the audience, there's just no way to really capture those comments. And we want to make sure that we get everything on the record and that we have an opportunity to look back and reflect on all of the comments that were made. So just ask that if you would like to make a comment, that is why we are here.

And I will ask you to come up to the microphone to make your comment. And I will ask you to introduce yourself and any organization that you're affiliated with. But please do not come up to the

microphone until I ask you to do to that or until I call on you.

We don't have too many people that want, that requested to make a comment. I just want to remind you if you decide that you would like to make a comment, feel free to fill out a blue card and bring it up to me.

So we're going to start off. Again, I will just remind everyone that you are going to hear a lot of different perspectives, a lot of different positions. We want to make sure that we show respect to everyone, even if we don't agree with that position.

I think our panelists did a wonderful job this morning of exhibiting that behavior for us. So we just want to follow that through the rest of the day.

So we only have, like I said, a few people who asked to make comments. And so once these comments are done, I have a comment that came in that I will read. We will go to the webinar to read any comments that came in from folks participating on the webinar. And then we're going to look and see where we are, how much time we have left. And we may go back to the panelists and start another dialogue with them. But

we will see how it goes.

For right now, we are going to begin the public comment period. And so I would ask the first -- actually, I'll just say the four speakers that we have, first we'll begin with Robert Stanton. Is Robert here? Okay. And then we're going to go to Subir Nag and then Pat Zanzonico and then Chandan Guha. So that's kind of the order, but I will call you when it is your turn. And we're going to start with Mr. Stanton.

MR. STANTON: Thank you.

- PUBLIC QUESTIONS AND COMMENTS

MR. STANTON: Good afternoon. This is more an opinion. And then the question can be opened up, and people might want to comment. I see the question of the medical event being used as a surrogate to talk about good medical practice. And that's not necessarily the intent of any individual, but that's the way it gets conglomerated together. Using a technical term, it's getting squished.

The safe use of radioactive materials I feel is the purview of the NRC and similar organizations functioning under agreements, but the practice of good, safe, effective medicine is not really the purview of that safety agency.

Now, I support activities to do that. I do believe that quality assurance is necessary for all medical practice. For example, the American College of Radiology and other similar organizations accredit external beam radiation therapy departments. And in the state I live in, New Jersey, in order to get a license to operate a linear accelerator department and treat patients, you have to be accredited by one of those agencies.

But that is different from a regulatory statute and inspection by non-medical personnel in this activity to review us. It's peer review, review by other medical professions, other physicians, other physicists. I'm a physicist. But that's not what I see coming out of an extension of the NRC mandate for evaluating radiation implants, prostate implants.

So that is the comment I want to make.

FACILITATOR SALTER: So now I am going to give the panel an opportunity to respond to that comment. And I can see Ron wants to make a comment. So I will go to him first.

DR. ZELAC: The Commission itself -- I'm not talking about staff, but the Commission itself has put out in the past a medical policy statement, four specific statements relating to how we would be

involved in the radiation, medical use of radioactive materials.

One of those statements has to do specifically with patients. And what it says, paraphrasing, is that the Nuclear Regulatory Commission will get involved with the protection of the public, which includes patients to the extent of trying to assure that what the physician ordered is what the patient gets. And it's from those words that we have gone to where we are now in trying to implement. Have we gone too far? Should we be doing less?

Those are clearly questions to be addressed. But that's where it came from, and that's why we are where we are at the moment.

FACILITATOR SALTER: Dr. Ennis?

DR. ENNIS: I appreciate the comment. We more or less agree. I do think there is a difference -- and where we draw that line might be somewhat debatable -- between quality assurance and protecting the public from radioactive misuse.

There are organizations that are coming together, patient safety organizations, in which data is being compiled on near misses and things like that under the protection issues so that physicians can

learn best practices and learn to improve while not being exposed to potential liability issues that seems that ASTRO I think that is the appropriate venue for these types of QI initiatives and medical improvement initiatives to the distinction, at least in the past, from an NRC regulatory point of view of you have misused radiation and risks to the patient.

FACILITATOR SALTER: Any other comments? Robert Dansereau?

MR. DANSEREAU: In New York, we are proposing regulations to require accreditation from either American College of Radiology or the ACR. And we had sent that out to all of our linear accelerator registrants. And we did not get any opposition to that notion.

So we're moving forward to that similar to what New Jersey already has in place. So we feel that to have a peer review like that process is very valuable.

FACILITATOR SALTER: Dr. Hagan?

DR. HAGAN: Yes. I agree with Ron's comments and concerns and agree more or less with them. I think the application of D90 is part of the engine which put us here today. And so I think the application of a specific metric that it was itself

and continues to be one that's under evaluation has its supporters and its detractors. To apply that and to apply that in a rigorous way transgresses into making a clinical decision, as opposed to a regulatory one.

FACILITATOR SALTER: All right. So we will move on to our next comment from Subir Nag. I stole this microphone. So you're going to have to go over there.

DR. NAG: Fine. Thank you very much for this opportunity. I have to start with the disclosure. I have been a member of the ACMUI before, and I have been deemed an expert from ASTRO, ACRO, ABS, et cetera.

However, the comment I am making today is in my capacity as a person with over 35 years experience in implant and other permanent implants, but these are totally my private views, rather than my official views.

We have been in this for over 35 years. Let's go back a little bit on the historical aspects. When we first started doing permanent implants, how were we prescribing or what were those directives? These written directives were very simple. We had the volume that you needed to implant. You take those.

You multiple that by five, and that was the number of millicuries required to implant a certain volume. Those were prescription in terms of activity.

Now, activity name has not turned. And it changed. You saw strength. So that's why now you have to prescribe by source strength.

So the whole onset of those for permanent implant only came after we did the implant. We found how many of these patients looked at implant goals. And when we kept on multiplying how many millicuries you need to prescribe, and now you treat with CT and three-dimensional dosimetry. You found what those became. So it was only, of course, not significance, not for a prescription. That was a mistake to use that through a written directive.

So it started with and should be wanting it to stay at an activity or source strength method of prescription. When you transplanted those and found out what the prognostics are that you engaged in, that's a different method, not a prescription method. I want to make this very clear to the regulators and to everyone questioned here.

The second thing, why would you then need to do something different for the removal implant versus a permanent implant? Why you are doing that or

removing for a permanent implant, why don't you do that for the removable implant?

The reason is very simple. In the removable implant, you decide what you want to implant. And then you have the time to do your calculation. You have the time to calculate your dose. You then can prescribe what those -- everything is under your goal. And then you remove it.

So if there are certain things that have changed, you can have that under your control. You cannot have that with a permanent implant when you have done that at the end. So in a permanent implant, if you have given a certain millicurie or certain source, if there are certain factors that are happening in the patient, whether the patient was getting it out or an e-mail or some other thing that is happening or a certain coming in and putting in a flap or anything like that, those factors should not change or should not matter what you did in the prescription, how long you did the prescription? If it went to the place where you did and that was your intent, then that is what you should be judged upon and not what happened inside the body.

So I hope this -- not many places have given this very clearly. And that's what I'm trying

to explain why there is a difference between a permanent implant and removable implant and why some of the confusion has taken place over the year.

Then what are the dangers that happen that are under the control of the authorized user? Well, we had a certain number of millicuries we wanted to implant into the organ, whether it's prostate, whether it's some other organ. And then the volume can change. We have heard many times the volume changed. So what if the volume changes? Well, if the volume changes, the dose changes inversely. And, therefore, your dose will change.

So you cannot then talk about those. You have to talk about, you know, what millicurie went in. So, for example, in permanent implant in the liver, you want to give a certain dose, but you cannot. So you give a certain number of gigabecquerel. And that goes into the liver. And in those permanent implants, it is activity going in.

The timing of the symmetry, we have talked many times. Whether you are doing it on day one -- and people have been asking, should it be 60 days, 30 days? Again, it depends also on the isotope.

In iodine-125, the half-life is 60 days. So probably it makes sense to do the symmetry at 30

days. Many do it on day zero, day 30, the volume will change. But in a palladium implant, the half-life is 17 days. Why should you do the same with the palladium population that you do for iodine? So the number of days will depend on how you do your implant, how you had planted your implant.

Then in imaging modality, many, of course, have talked about, your dose that you will get will depend on the imaging modality ultrasound with the CT, with the MRI, the contouring, whether the contouring was done on -- the volume has always been different from the way it was implant.

There was a meeting right here in New York in 2002. I was part of that meeting. We had about 12 of the top radiation oncologists and physicists who were involved in prostate implant at that time. We all went to the same prostate contours. And we were told to draw the contour of what we thought was the prostate. And that was adherent radiation more than a factor of two. Then if on the same prostate we wanted to see what the dose would have been, it would have been growing by a factor of two.

The planting margins. We talked about the planting margins. Therefore, the planting margin is different by individual petitions. So that when we

are talking about a treatment site, talking about -- Dr. Zelac had talked about treatment sites -- we have pointed out several times that you cannot say treatment sites to mean exactly. It should be called as the planting target volume.

It's the volume you intend to implant, not the prostate volume. The prostate volume is immaterial. Depending on your philosophy of implant, if you want to do belly implant, central implant, where did you plan to put the seed so that if your dose, it depends on volume.

The other thing, you are doing it for a D90 and you say more than 120 percent will be a medical event, we are going to see that if you look through all of the reports over the years, you get better control on those groups who have more than 120 percent. So you're going to have people who have medical events are going to have better control rates.

So this is totally ridiculous. So I'm just pointing it out, how ridiculous it will be if we are going to insist on a dose-based matrix.

The other thing is a 20 percent deviation, in addition to permanent implant, the implant was a removable implant. This 20 percent is something we would want NRC to think about. Why? Because there

are two different areas you have to think about. One is your target volume. If you get the higher dose in your target volume, you are going to get a better control rate.

So if you get more than 120 percent, you are going to get a better control rate with the resource so long normal but not yet overdose. So if you are getting higher than 120 percent in your target volume, that's fine. I don't think that should be a problem, more than the normal but not yet overdose.

So then you say, "Well, the normal resource is not yet more than what that yellow one, 5 sievert or 50 millirem and more than 50 percent overdose the normal, will that work?" No because the 50 percent overdose is fine, but the 50 millisievert came from something from a total body exposure, not from permanent implant, where the volume is extremely small.

Fifty millisievert or 50 millirem was more like -- more volume by itself. The whole body exposure, yes, but external means whole body exposure at 15 millisievert is fine. For a permanent implant, 50 percent overdose and millisievert cannot work unless the expected dose was already very high. If the expected dose was extremely low. Fifty percent of

an extremely low dose is certainly by itself.

The other question that you had talked about and others had talked about was when it is something that the public should worry about and people say, "Well, it's not necessarily a problem." No matter what you call it, the moment you have a medical event, number one, but basing it, number two, the massive volume of work that is required within by the NRC, by the institution but not by itself. Plus, if it was an underdose, many places will now seek additional treatment that is not only unnecessary but could be harmful.

So, first, you think you have an insufficient dose to the patient or to someone else. "Oh, yes. You have insufficient dose. You need another external." And then you would really add harm because you had an inappropriately called medical event.

So I would say that the current definition would work, but if they are a patient practice, like volume changes and so forth that are happening because of the patient practice, those should not be called medical event.

So having all of this, I have also been an NRC consultant. And I have examined many medical

events or potential medical events. And what I have seen is that if you use an activity-based definition of medical event, you can really catch the bad actor and not in the same net as those that are proffered. So I would support a definition of medical event that is activity-based and definitely not support a dose-based medical event. And you really should not separate out prostate from non-prostate from permanent implant because they are all permanent implant. What you should do is word your definition in such a way that it will work both for prostate and non-prostate.

Thank you very much.

FACILITATOR SALTER: Thank you.

I am going to go back to the panel and see if anybody wants to comment on that before, anything that Dr. Nag said before we move on. Dr. Zelac?

DR. ZELAC: Thank you for that very comprehensive coverage of our essentially subject matter for the day. I appreciate very much getting your opinions on these various issues.

There are two statements that you made that I would like to at least comment on. The first had to do with what is now in the regulation defined as the treatment site.

The regulations that we have now were

formulated in 2002. And at that point in time, the intent of the Commission was to move from what had been a very prescriptive regulation in many respects towards a more performance-based regulation. And, with that in mind, where there could be simplification, where it didn't have to be very specific about something, it was introduced.

Treatment site was intended to permit the physician to make the definition of what the treatment site should be, be it PTV, GTV, CTV, whatever. It was up to the physician to make that decision and to go forward with that.

So, you know, the fact that it is open to input on an individual basis by the involved physician to his or her preference is what we thought was the way to go. If you are suggesting that we be more specific and more essentially prescriptive in saying PTV, as opposed to treatment site, we can go in that direction or at least we can consider going in that direction, but I'd like to be sure that that's what you were really intending.

DR. NAG: I think I should --

FACILITATOR SALTER: Just introduce yourself again so the people on the webinar know.

DR. NAG: Sorry. Subir Nag.

I should like to clarify. What I am saying is that the treatment site that the physician is intending, really, where we are planning to put our radioactive materials, what that, therefore, really is the planning. However, the mistake that the people, the inspectors and the people, who are trying to find out if this is a medical event or event is that they are thinking it is prostate organ.

So I think maybe we need clarification introduced that the treatment site where we are going to is the planting area that the authorized user intends to place the radioactive material such that the area they want to treat will be treated.

So you need to have that clarification. Otherwise, the person who is examining it thinks that, well, treatment means the prostate and, therefore, if the prostate is not getting the dose or the millicuries you want to have, it is, therefore, a medical event.

So I think it is more a clarification that is needed for the people who are both prescribing and to the inspectors.

DR. ZELAC: So you're basically saying that the use of the words "treatment site" is okay as long as there is a clarification as part of the rule

as to what that means --

DR. NAG: Yes.

DR. ZELAC: -- by definition?

DR. NAG: Yes. Yes. That the treatment site refers to the area that the authorized user wishes to place the radioactive material into, which is the same as the planting target volume basically.

And the margin that you are allowed to have would be up to the authorized user. He's the only one who knows where he is planning to put the seed.

DR. ZELAC: Okay.

FACILITATOR SALTER: Does anyone else on the panel want to comment on the treatment site descriptor? Dr. Welsh?

DR. WELSH: Thank you.

I think that the term "treatment site" may have originated in an era that predates the precision of our definitions that we use today, such as gross tumor volume, clinical target volume, planting target volume.

And now if it is clear that NRC and inspectors understand that the so-called treatment site is up to the physician's discretion as GTV, CTV, or PTV, I think that it would be perhaps preferable to

be less prescriptive and to allow the continuation of the term "treatment site" so long as it is understood that treatment site might in some cases be synonymous with PTV, in most cases synonymous with PTV.

Perhaps less prescriptive is better in this context as long as inspectors and NRC understand, and it sounds like they do now.

FACILITATOR SALTER: Dr. Hagan?

DR. HAGAN: Just one addition is that whatever our metric turns out to be, that treatment site flexibility is helpful, but the written directive should include the authorized user's definition of the treatment site for that procedure. So we can hold the authorized user to accomplishing that which he intended.

FACILITATOR SALTER: All right. So let's bring up our next --

DR. ZELAC: Excuse me?

FACILITATOR SALTER: Oh. Sorry. Dr. Zelac wants to make a comment?

DR. ZELAC: No. I wanted to bring up another issue with what Dr. Subir Nag has said.

FACILITATOR SALTER: Okay.

DR. ZELAC: And this has to do with the 50 rem, 50 percent. The 50 rem was there essentially to

provide a minimum dose, below which there would be no consideration of a medical event.

Now, what we have clearly heard several times today is that if you are going to have a 50 percent as one of the criteria -- and that's still debatable whether it should be 50 or 100 percent or whatever, that there still needs to be a minimum dose below which you simply do not consider this as a potential medical event. So if the question is, if it's not 50, if that's too low, where should it be?

DR. NAG: Subir Nag. From a linear standpoint, that has to relate to some normal, usual arrangement. It cannot be the same for official with a 10,000 centigray or some other official, where you are going to harm the official with 1,000 centigray. So it has to have some relation for the normal, usual event.

But the problem is then you will have to state that for the rectum, 6,000 centigray perhaps. Then you have to take for each individual organ what that limit would be.

That cannot be 50 centigray because that small dose, 50 percent of that dose would be of no significance at all. But if you take that in the rectum, it cannot be more than 6,000. If there are

60,000 or 60 Gray once you explain and you are having 50 percent more than that, definitely that would be helpful.

So there has to be some correlation with normal tissue.

DR. ZELAC: Well, this is Dr. Zelac.

That clearly presents a regulatory challenge to set up something of that nature, but I hear what you are saying.

FACILITATOR SALTER: Dr. Welsh wanted to comment.

DR. WELSH: Again, as I've said before, whenever we are talking about doses that if exceeded would represent a medical event, it must be tied to a volume or an area. Otherwise it's essentially meaningless and extremely difficult to enforce.

And so when we are talking about parallel organs versus especially parallel organs versus serial organs radiobiologically, it is critically important and a standard to define an area or volume. Otherwise any number that we come up with is not going to have much value.

FACILITATOR SALTER: All right. So let me ask -- Dr. Welsh?

DR. WELSH: Dr. Nag brought up a number of

important points. So I'm just going to comment on one of the points brought up, which was the post-implant dosimetry deadline. And we have heard that it is a very controversial point. We don't even have consensus within the ACMUI subcommittee.

AAPM has recommended no deadline, but I can appreciate and many can appreciate that if we are saying that if post-implant dosimetry is appropriate and should be done, a regulator is going to say you have to have some kind of deadline. Otherwise this is unenforceable.

And, as Dr. Nag has brought up, the isotope chosen, palladium-103, cesium-131, iodine-125, they have different half-lives. And, therefore, it can be a little bit challenging to have a one size fits all for the deadline.

But it might be reasonable to say that if a deadline is proposed, that it be well beyond not the half-life of the isotope so much but the edema half-life. Otherwise you would always have potential challenges with this volume concern. And, therefore, a minimum of 60 days might be appropriate if NRC insists on having a deadline at all.

FACILITATOR SALTER: Any of the panelists want to? Dr. Zelac?

DR. ZELAC: Just a comment. The question of what the time factor should be has come up several times. Our understanding was that typical clinical practice for the longest isotope that was used for implantation, longest life isotope, iodine-125, was to make the determination of source position and, therefore, the dose determination at 30 days typically or less but typically not more than 30 days.

So the working group that put together the re-proposed rule said "Okay. If standard practice would be for the longest lived isotope doing this at 30 days, give them twice as much time. Put the limit at 60 days and say it should be completed by 60 days." That's where the 60 days had come from. And, you know, that was kind of the rationale for establishing it to begin with.

Clearly if the patient doesn't show or is not available, you know, that is patient intervention. And all bets are off in terms of there being a medical event because of it not being done within the 60 days. But that's where it came from.

FACILITATOR SALTER: Dr. Nag, please go up to the microphone.

DR. NAG: I'm Dr. Nag.

I think, Dr. Zelac, what you say is

correct. I think 60 days is a practical suggestion. Now, what if the patient doesn't come? I think that's very easy to show. What the physician has to do is to say that, you know, you have to make an honest attempt at getting the patient back, normally at 30 days, or zero days, one day, or 30 days. These are the three most commonly used.

And if the physician makes an honest attempt at getting the patient back and documents, we have written a letter that the patient hasn't come back, at 45 days hasn't come back, and at 60 days, we have lodged, really, a time for the patient to come back, the patient has not come back or the flight was not available or whatever, if that is not documented, that will not be a medical event. I think it can work out perfectly.

FACILITATOR SALTER: All right. So Dr. Nag has brought a number of topics up. And it seems like we had some good discussion going. Before we move on, I just want to offer the panelists a chance to comment on any of the comments that Dr. Nag made.

(No response.)

FACILITATOR SALTER: All right. So let's have our next speaker come up. It's Pat Zanzonico. And I am going to ask you to go over there, one,

because I took this mike and, two, you're blocked by the podium from seeing the whole panel. Please just introduce yourself and any affiliations you have.

DR. ZANZONICO: Good afternoon. I'm Pat Zanzonico from Memorial Sloan-Kettering here in New York City. And I'm also a member currently of the ACMUI.

I actually have questions more than comments. The first is there seems to be a consensus on an activity-based definition, rather than a dose-based definition for medical events in permanent implant brachytherapy of the prostate from all I hear. And it makes sense to me.

The question I have is, would there be scenarios, practically speaking, where such a definition would not capture a clinically significant medical event?

And I'm thinking, for example, where there is unintended seed bunching within the prescribed treatment volume. So that by the 20 percent activity criterion, it would not be a medical event. But, yet, it would be not what was intended. And it would have a clinically significant impact. And if that's the case, what practical additional criteria could be introduced to capture that as well?

FACILITATOR SALTER: So let's go to the panel first. Comments on that question? Dr. Hagan?

DR. HAGAN: Well, that's an issue that I think each of us have thought about and opined and identified comments from outside and inside brachytherapy community about. Practically, looking at those implants from Philadelphia, there was one implant where the activity metric would not have picked up a significant deviation from the planned D90. And that implant was one where the physician changed his design coverage to eliminate part of the prostate. And so when reevaluating that implant in terms of total coverage, there was some reduction of anterior coverage.

So it identifies two things that are very helpful in terms of answering that. And that is that the source distribution at the end of the procedure is something the physician routinely comments on as part of the operative note. And requiring that attestation so that there is a verification by the physician at the end of the procedure that his source distribution is as he intended it I think gives you a way to not only control but to verify with a written signature, with written attestation the possibility that you raise that seeds have an unusual and an unplanned and

unsatisfactory distribution has occurred.

The only condition that you could imagine where that happens is where the seeds have been poorly distributed within the prostate. And, yet, an incorrect statement, a misstatement is made in the operative note. So requiring the operative note to comment on the seed distribution I think gets you about as far as you're going to get with that kind of evaluation.

Trying -- and we have done this, and there is a small literature on it. Trying to apply some sort of sectoring technique to the prostate evaluation to do seed counting per sector sounds like a good idea, but in practice, it's very difficult. And once the physician has decided to omit part of the coverage, then sectoring the residual volume to try to answer that question becomes an impossible event --

FACILITATOR SALTER: Any other panelists want to weigh in on that?

DR. ENNIS: I agree.

FACILITATOR SALTER: Dr. Ennis?

DR. ENNIS: Sorry. Dr. Ennis.

FACILITATOR SALTER: Yes?

DR. ENNIS: Also, just trying to help NRC think ahead, there are trends to start to move towards

implantation of tumor more intensely or exclusively and not necessarily trying to treat the whole prostate. We would want to introduce a regulation that would immediately stymie the progress of the field.

So allowing, as Dr. Hagan said, an attestation of what my intent was, what it might be, maybe it is not a protocol or whatever, and then confirming that with the post-implant dosimetry is the most flexible way I think to deal with this problem while still giving the regulators definitions that can be verified against intent.

FACILITATOR SALTER: Good. Do you have a second?

DR. ZANZONICO: Yes, I have another question. And this is related to the issue of terminology, but I think it has more tangible implications than just semantics.

There has been some discussion about is there an alternate term for "medical event," less ominous, having less medical, legal implications? The term I was thinking of is a "sentinel event." And the importance of it is not so much the difference between a sentinel event and a medical event but that if it's reasonable to build into the regulatory definition of

such an event, that by definition it has no clinical impact on the patient, but it simply signals an apparently suboptimal practice that if unchecked could eventually lead to a clinically adverse event.

So it seems that that kind of in-between type of term would overcome a lot of the objections of the clinicians and others to a medical event and all that it implies. Yet, it would satisfy the desire of the regulators to be able to identify these sorts of suboptimal things that can and should be addressed before progressing.

So, Dr. Zelac, is that something that is appealing at all to regulators and so forth?

DR. ZELAC: I can only speak for myself, and the answer is yes.

FACILITATOR SALTER: Any other panelists want to? Dr. Hagan?

DR. HAGAN: Yes, but back to the same issue, the issue is not so much what you call it but what you do with it. If you call it a sentinel event, which is an excellent description of how we use this event, but you require disclosure to the patient and you require reporting to a referring physician, then the pejorative implication is there, no matter what you call it.

So I think that you need not only to have a new lexicon, but you need to have a divided intent of multiple reporting classification or at least two reporting classifications.

DR. ZANZONICO: Well, my thought was that it would not be a disclosable event. It sort of gets into the work of quality control, but, again, it does seem to satisfy the concern of the regulators to be able to identify suboptimal practice before it reaches the level of clinical impact.

FACILITATOR SALTER: Mr. Dansereau? And then we'll go to Dr. Ennis.

MR. DANSEREAU: In our proposed regulations for QA for therapy, we do have proposed a recording of near misses. In our proposed regulations for QA for therapy, we do have a provision in there for near misses. We would expect the facility to record that event, look at the event, look at it for generic implications, and take any steps they feel appropriate to avoid an occurrence that would be worse or maybe meet the definition of a medical event.

FACILITATOR SALTER: Dr. Ennis?

DR. ENNIS: So I think the physician community welcomes opportunities to improve their quality. We just need to make sure the key issues

earlier, discoverability, protection, anonymity. If it's available to a lawyer, if it's available on the website, it's a huge problem that will not foster growth and development and quality improvements.

And, again, that seems more like a quality assurance, a patient safety organization-type activity, but I suppose it might be able to be done by NRC as well. Those kind of parameters I think are key.

FACILITATOR SALTER: Dr. Zelac? And then we'll go to Dr. Welsh.

DR. ZELAC: When I gave a yes to your question, it was presumptive of there being, in fact, two classifications, what we now are calling medical events, which would have serious clinical consequences or potentially serious clinical consequences for the patient involved and the sentinel events, the precursors, if you will, something like a near miss.

But in terms of what would be done with that information, I think yes, the facility should be utilizing it for self-improvement, but some of those have implications for other facilities as well. And to that extent, those types of occurrences ought to be noticed to the regulatory body as well.

DR. ZANZONICO: They could be anonymized

and still serve the same purpose.

FACILITATOR SALTER: I think we were going to go to Dr. Welsh. And then we'll go to Ms. Eisner.

DR. WELSH: I'll continue with the same logic and line of discussion here. I do agree that it might be very reasonable to have another category, in addition to medical event. And "sentinel event" seemed like a very reasonable term for it.

I think that things that qualify as medical events would probably be something that would need to be disclosed to a patient. I would think that things that fall into the sentinel event category could be things that would have absolutely no bearing on patient outcome whatsoever, such as post-implant dosimetry was done on day 61, instead of within the first 60 days, or written directive was not put in the chart or physicians and physicists at this institution were not trained in definition of medical event.

Those should not be medical events, but they could fall into this second category, the sentinel event, and have no bearing on patient outcome and, therefore, not be something that needs to be disclosed.

I might disagree with some others about whether or not something that does meet the definition

of medical event should be disclosed to the patient. My personal perspective is that it should because I wouldn't want my patient to find out from somebody other than me that their care was labeled as a medical event.

Irrespective of that, I do concur with the concept of a sentinel event or some other terminology that is not so concerning and distressing.

FACILITATOR SALTER: Ms. Eisner?

MS. EISNER: I certainly agree with the sentinel event.

FACILITATOR SALTER: Can you just pull that a little closer? Our folks on the webinar are telling us they're having trouble hearing.

MS. EISNER: I also agree that near misses or anything that could impact overall on other patients as well should probably be reported to a regulatory agency as well as internal review to be looked at.

As far as being reported to the patient or not, personally I would want to know, but there may be a patient that might not. And patient autonomy should come into play with that. A patient could simply be asked, "If something happened," maybe a directive or something, "would you want to know about it if it

doesn't impact on your are or outcome?" And many patients might, and some patients might not.

But I think, again, the transparency is important and the trust be there. Like Dr. Welsh said, you know, certainly he would want to share with his patients that. And that might be part of how the physician views his obligation to the patient.

DR. ZANZONICO: Again, this is a purely informational question, but, just to clarify, does the time of post-treatment dosimetry have any clinical impact? I mean, intuitively to someone really unfamiliar with this, it seems for a permanent implant, it would not because there is nothing that can correct it that can be done after the fact or am I wrong about that? Is there a clinical significance of the time of post-treatment dosimetry?

FACILITATOR SALTER: Dr. Welsh?

DR. WELSH: I'll take the first stab at an answer to that. I would say it most definitely does have clinical importance. And, as we have said many times, the prostate is a bit unusual. And this is why I personally feel that it might deserve a separate category in that it does swell after it has been traumatized by numerous needle sticks and foreign body implantation, irrespective of the radioactivity.

And, therefore, you will have changes, including edema, which tend to resolve on an exponential curve back to its original volume, but that curve is nothing like the decay curve of radioisotopes. It is very dependent on the individual and varies significantly from patient to patient.

If we picked the time for post-implant dosimetry and mandated that it had to be at a certain time and that time was within resolution of the volume changes, the edema resolution, you would wind up with significant problems if we adhered to a dose-based criteria.

If we don't have a dose-based criteria, it's still a problem because we often would like to know what the D90 is for our patient, not with respect to regulatory purposes but just as a clinical guideline for ourselves and something that will tell us what to expect with this particular patient's outcome.

I think that if there is to be a deadline, it must be beyond the edema half-life. And that half-life typically would be within a 60-day period.

I know that there is some debate in the literature about when the best time for a D90 calculation might be with I-125. Most of us feel that

30 days is quite reasonable, but I have seen estimates that go beyond that, which is why I don't feel very strongly that we have to say 60 days is the limit. I'm flexible, but I would say shouldn't be anything less than 60 days.

DR. ZANZONICO: This is Pat Zanzonico again. Is there any upper limit? In other words, is there a point where, for example, you may get -- "atrophy" perhaps isn't the right word, but you get the opposite of swelling that can give you a spurious result so that there should be an upper limit as well in that respect.

FACILITATOR SALTER: Dr. Ennis?

DR. ENNIS: So what you have in play are really two things dynamically at the same time, which makes it so difficult. It's not just the edema half-life but the seed half-life, so for different seed half-life.

A cesium implant really needs to be scanned at some earlier time and an iodine implant for the same type of edema, but we don't know quite now what that ought to be and particularly for that particular patient because they don't know what his edema is going to be.

So I really think we have to leave a lot

of flexibility to the clinician to make the right judgment. We can put some outside end time, 60 to 90 days or something like that, as probably being reasonable and allowing clinicians to practice.

Some people like to do day one. And that is reasonable. Cesium, maybe they should do it at day 7, palladium 17 days, something like that. So there needs to be a lot of flexibility in terms of you can have an error, though.

And if you wait too long and the prostate has shrunk down and the dose that you are calculating is not really what was delivered because you waited so long the prostate now is worse. So there is a potential on that side to prescribe that and to decide, us sitting here, what that is without -- we really have no clue.

Also, you know, for an implant that is too weak, for example, you can fix that. You kind of alluded to is there anything you can do with this information?

You can re-implant to get some external being to make up for that. And although that is not often necessary or done, it can be done. So that there is something that can be done with the information over and above just documentation.

FACILITATOR SALTER: I'm going to give Dr. Nag an opportunity to also respond to that.

DR. NAG: This is Subir Nag. Yes. I want to make some comments to what has been discussed just now that prostate is different from other organs. I'm sorry. I don't think so.

If you implant -- and I have implanted other organs. If you have a solid organ, pancreas, lung tumors, not the surface implant but actual lung tumors, when you implant them, there is some edema afterwards.

And there are two regressions. One is the regression of the edema. Second is the regression of the tumor. So when you have given enough of those, the tumor also regresses.

So there is some initial increase in the volume. And then the increase in the volume goes from the regression of the edema and regression of the tumor volume. So both of those are taking place.

Now, why are people doing the dosimetry at 30 days? It would make more sense to do the dosimetry at day one. The reason that we're doing the dosimetry at day 30 was when you did the dosimetry at day one. Because of the larger volume, they were finding they were getting a much lower dose. And still they said,

"Well, let's wait for the edema to put down and then do it."

But if you are waiting too long, then if you have a problem, you can't do much about it because the time period had gone. And, therefore, when people generate that between the dosimetry on day zero and normally you are not using the dosimetry parameter but you are using an activity-based parameter, you found insufficient activity, you could still make the decision, then, "Do we put in more seed" -- many people were doing a second implant afterward -- "or do you add external beam?"

So that is the reason why some people do it on day one, some people do it on day 30. I think it applies to prostate as well as to other organs.

FACILITATOR SALTER: Okay. So just going back to the panel before we go to our next speaker, are there any other comments? Dr. Welsh?

DR. WELSH: I would agree with what Dr. Nag just said, that if we come up with the appropriate definition, there is no need to distinguish between prostate and other types of permanent implant brachytherapy.

So that is why it is critically important to come up with the appropriate definition. I think

that the ACMUI ASTRO definition will fit that bill.

If NRC does not adhere to these recommendations, I think that the question still remains on the table in that prostate. Lung tumors inside the pancreas are examples of organs that do experience volumetric changes, anatomic changes secondary to edema, atrophy, tumor regression, et cetera; whereas, the lung implants, the mesh implants, are susceptible to seed rearrangement as part of the operative procedure and, therefore, might be conceptually quite different.

However, the currently proposed definition may very well be appropriate for both categories. And therefore, there may be no need for subcategorization, after all.

FACILITATOR SALTER: All right. So I am going to ask our next speaker to come up to the mike: Chandan Guha. And if you can just introduce yourself with any affiliation or --

DR. GUHA: Yes. So I'm Chandan Guha, professor and Vice Chair, Department of Radiation Oncology at Albert Einstein College of Medicine in Montefiore.

I have been doing seed implants for more than 15 years. And I really thought that it was --

all the panel discussions, you know, many of the issues that we deal with every day are being raised.

So I really have two comments, clarification, which I would come to, but before that, I would like to start with an introduction about what I am saying and why I am saying.

Imagine the two things we are dealing with. One is this definition of prescription or written directive. The other is the event. So these are the two things we are discussing in this rulemaking event.

So let's imagine that I prescribe a surgeon, that you go to operate on the prostate, you remove the whole prostate. That was the prescription which was given to the surgeon.

We know very well that the surgeon goes with his best of interest, tries to remove the whole prostate, and, yet, over and over again, you will have positive margins, which is basically meaning cancer being left behind.

The surgeon comes back and says, "That's okay. You know, I tried to remove the prostate, whatever I could see, but things were left behind." That's the biology of the disease.

So prescription is good. Prescription is

intent. And that is our written directive. And this whole prescription issue belongs to a subjective process and objective criteria.

As we saw over and over again, there are many subjective things, some of which we know about, such as volume increase of the prostate, the half-lives, the edemas, which will be led to overdosage or under-dosage. And there are many other things which we don't know because the science is not good enough, such as the biology of the disease, whether the prostate cancer crawled out of the prostate, the sensibility of the patient, one, to patient B. These are all so subjective, but we don't know how to define them.

The only thing which is objective in all of this parameter as a physician is that when I go to implant, I know the volume which I got. That is the only objective thing I have to guide and to shape the prostate because I am measuring imaging to find out how the prostate looks.

I also know the type of seed I want to implant. You know, it can be that I intended to go for iodine-125 but somehow there was a mistake and I ended up with cesium or palladium. That's a misadministration.

I know the activity which I chose per seed. And to make that volume work, how much I have to implant, how many seeds I have to implant, which means, therefore, the only thing which is objective for me at that day is my inter-operative plan.

I looked at it. I consulted my physicist. And I decided as a technician that there are certain areas which I will not implant, there are certain areas I will implant more.

So all the volume, the octant and sextant or whatever you call it, quadrants, it doesn't matter. I'm seeing part cut. There will be a procedure how the dose distribution is. And I did it according to what I felt was there.

Now, prostate implant, I frequently, all my patients, I tell them to come back. Now I am going to do a post-op CT scan. From the patient's point of view, all they ask, "Can you see my cancer?" They don't care, you know, what you are doing because I can't change anything in the seed implant once it has been done. They only care for whether I can check my cancer.

And most of the time I keep on telling them "No, no, no. This is really done for my quality assurance. This is for my science. This is for my --

you know, so that everything is good for you," et cetera. But, in reality, from the patient point of view, this post-implant dosimetry and other things, which we do all the time from their perspective. It's not the cancer which we see.

So, with that, you know, brief introduction about that different specialties have different prescription, it's okay for the surgeon to have positive margins and leave cancer behind. And it's not a misadministration.

And, yet, we have all of this discussion about what we are going to do because radiation is very different. And we don't want to harm our patients. And, therefore, we need some kind of consensus.

So I have just two comments and clarifications, really. The question of inter-operative plan, can that be your written directive that I checked? You know, I know that I am under-dosing, 84-year-old. Deliberately I am under-dosing the bladder neck and very deliberately under-dosing the anterior prostate.

I'm more or less "overdosing" because I put two, three seeds where the cancer appears to be there. I put seeds in the seminal vesicles. Maybe

it's the best of the prostate where the cancer could spread and left other areas because I don't want them to have any side effects.

So, therefore, when I check the plan, cut to cut to cut, and I sign that plan, that is my written directive. That is my prescription.

So that I will wait for your answer on that, and then I will go to the next point.

FACILITATOR SALTER: Okay. Would anyone like to address that or respond to that? Dr. Zelac?

DR. ZELAC: I presume we were directing that more to me than anyone else.

(Laughter.)

DR. ZELAC: The current regulation that we have with NRC permits, as I mentioned before, for a pre-implantation written directive statement. What the intent of the physician was, to make changes or modifications up until the time that the first seeds are implanted. Once that is done, that's all. It's finished. And that's essentially the target that the physician has stated that he or she is trying to achieve.

However, the same regulation also calls for completion of the written directive once the procedure, the implantation procedure, is done. And

at that point, the clinician who has conducted it then makes another entry, either in terms of dose or in terms of total source strength implanted in time, which in this case for permanent implant simply has to be stated that it's permanent.

So, even with the current regulation, as it stands, there is time at the end for the physician to enter what it was that was, in fact, achieved. And that being the case, the medical event is only then based on whatever information the physician put in to complete the written directive.

So if at a later time, for example, it was determined that the activities of the seeds were incorrect, the wrong seeds had been picked, you know, you had two batches and you picked the wrong one and the written directive had been completed by entering in the total source strength implanted and you are more than 20 percent away, clearly that would be a medical event.

If the physician had chosen to say, "Well, based on what I had originally thought in terms of where I wanted to put dose, put activity, which resulted in dose, I can state what I believe the resultant dose to be. Maybe they might do a dose determination right then, first day, day zero. You

know, so that's what the physician would be held against in terms of determining whether or not a medical event had occurred.

So that kind of flexibility is here, but the inter-operative planning, where you essentially are deciding on the fly what it is that you want to accomplish and working towards that. It can be accommodated with the current regulation, but it's a little cumbersome, frankly. And that's something we would like to try to change.

DR. GUHA: What is the conversion?

DR. ZELAC: It relates exactly to the fact that it is very difficult to come up with a clinical metric that has meaning that can be placed into the written directive in terms of dose. That is the problem.

You have D90. It doesn't fly. As far as I'm concerned, it doesn't fly. It's okay for under-dosing, but it really has no bearing for overdosing for prostate implant.

So my position -- and this is my position, not the agency's necessarily, is that there is a lack of a good metric to use if dose was what the physician chose to finish the written directive with, much better to finish it in terms of total activity

implanted. You know --

DR. GUHA: Any comments from Dr. Ennis or Dr. Welsh?

FACILITATOR SALTER: Dr. Welsh?

DR. WELSH: Thank you. First I'll try to reply to your question. I'll start by saying while I don't disagree with the current regulations, I find them a bit confusing and somewhat cumbersome. I think your point was, can the written directive be modified intra-operatively while you are observing things in the operating room while the seeds are being placed, needles are being placed, and the real time planning is being used.

That is something that we often do now. Most institutions have moved in that direction. So it is a dynamic process, but things can change compared to the static situation at the time the first seed is placed. Things do change.

And, therefore, I would be in favor of having a written directive that could be modified up until the patient has left the recovery room. I think this is one of the proposals that the subcommittee and others have put into effect which would allow intra-operative observations to be incorporated into a written directive.

I hope that answers your question. I would like to just say that as an editorial, you started out by mentioning that sometimes surgeons will aim to remove the prostate, but that is not achieved. There often is positive margin.

There are things that can be done about that, but it is not a federal event. It's not reported to an agency, a federal agency, like the Nuclear Regulatory Commission. And that puts brachytherapy at a bit of a disadvantage.

And it does remain important to emphasize that this is a safe and effective treatment with a proven record that can be tarnished by some of the recent negative publicities that have occurred surrounding the fact that the term "medical event" is too loosely applied and the current definition is in sore need of some upgrading and repair because in my opinion a medical event using the current definition is not nearly as significant as leaving a positive margin during a surgical procedure. Yet, one doesn't have to be reported. The other one does. Of course, they both need to be reported to the patient.

FACILITATOR SALTER: That's okay. Why don't you finish your question?

DR. GUHA: Okay. So that brings me to the

second point, but that's really right that while a positive margin, for example, now we all had robotic surgery, which is coming in most community practice. And, as we all know, when we do the robotic spectrum, there will be more and more positive margins.

It's not an event. It's not an event to be reported. It's just between me and my patient. So obviously the definition of events come into play, that that will be the connotation of event versus connotation of this is my best therapy which I can provide. And in the process, we have an art where we will have extra-prostatic extension or extra-prostatic seeds, et cetera, you know, needs to be considered.

One of the things I would really think from patient advocacy point of view or from our point of view, why am I so confidently saying what I am saying about that it doesn't matter, the D90s and so forth, is because over 15 years, very importantly, I have taken all of the data which all of my patients had. And I know how my patients are doing over this period of time.

So I would really encourage that, both from a regulatory point of view or insurance point of view or whatever point of view, like when we get accreditation, we have a tumor registry. So why not

have registries for all of our patients which are going through the treatment?

And over time, if I have to be accredited by X or Y, a board, then my registry gets the same in five years, how many patients had what. I mean, what was my D80/D90? It's immeasurable. It's like over the time that this was my practice pattern and this resulted in good patient care.

And so that registry would help a regulatory commission to figure out whether the practice is good or bad. I would like that.

FACILITATOR SALTER: Thank you, Dr. Guha. So anybody want to make any final comments? Ms. Eisner?

MS. EISNER: Certainly, from the patient advocacy perspective, I think that is an excellent idea and certainly would provide excellent information I think for following patients as well as making recommendations for other patients.

FACILITATOR SALTER: Dr. Ennis?

DR. ENNIS: I think the implications of what Dr. Guha is suggesting are that this be done across the house of medicine in that a surgeon, a radiation oncologist, a medical oncologist maintain a registry of their patients and report their outcomes.

That again feeds into this notion of there being a patient safety issue across the house of medicine, as opposed to a regulatory, a radioactive sources issue.

MS. EISNER: I'm not sure if that's what he meant or not.

FACILITATOR SALTER: Pull that microphone a little bit closer.

MS. EISNER: Yes. I'm not sure if that's what he meant unless I misinterpreted what he said.

DR. GUHA: Well, I meant both. So yes. I mean, from a radiation point of view, we can have a history. When I teach my students, I tell very easily that you can give a gram of Cisplatin. There are many ways you can excrete it, you know, through the urine, through this, through that. You gave one gray of radiation. You cannot excrete it. So, therefore, all this discussion is because of this idea about radiation and the "terror of radiation."

So yes, we need it raised before radiation, but I completely agree with Dr. Ennis that if we had a regulatory commission for the surgeon to leave positive margins behind and the amount of money which is being spent to treat these patients and the toxicity they have, I mean, that's of a larger

magnitude than what we caused with the seed implant, you know, the toxicity.

I mean, I can tell my patients, look at their eyes, and always say that when I do a combination of radiation or seed implant with aggressive disease, I am giving the best treatments with the least of toxicity. I can do the same for many other people.

FACILITATOR SALTER: Thank you. All right.

Anybody want to? Dr. Ennis?

DR. ENNIS: I just wanted to clarify with Dr. Zelac. So the NRC is okay with the notion for Dr. Guha that at the end of the procedure, you noticed what you intended to do and if you purposely put seeds more intensely where the tumor was and less intensely at the bladder neck because it was an old guy and you didn't want to cause complications, that's acceptable? And that creates the standard to which your post-implant dosimetry would be assessed?

DR. ZELAC: This is Zelac. There is more detail in that proposal and in that explanation of what is possible than appears in the regulation. The regulation simply says at the conclusion of the procedure, you enter either the dose or you enter the

total source strength implanted and the treatment site, period.

You know, in terms of how the sources were distributed, where they went, whether they went into the bladder, rather than the prostate, that's not part of it, you know, unfortunately. And that is part of what we are trying to change.

FACILITATOR SALTER: All right. We have three more speakers that have signed up. We have Ralph Lieto, Leon Malmud, and Jean St. Germain. So we will start with Ralph Lieto.

MR. LIETO: I was hoping to be last. My name is Ralph Lieto. I am a medical physicist. I am here as part of representing the AAPM.

I had a couple of comments and questions. I had a clarification question for Mr. Dansereau on the summary slide. You mentioned that there were 1,200 cases that had been reviewed and that 3 percent of those 1,200 cases were found to be medical events based on the dose-based criteria?

MR. DANSEREAU: I don't have details on that because that was assessed by the licensees. And in that regulatory information statement from Wisconsin, that's how the data was presented. The licensees did that based on the regulations in

Wisconsin, which are compatible with NRC's.

MR. LIETO: So it's based on a recent review of events that have not yet been reported into a database?

MR. DANSEREAU: I don't know if those events have been reported or not. Those events are from 2003 forward.

MR. LIETO: That's a lot of cases.

MR. DANSEREAU: Just in clarification -- well, not in clarification, but in one of my slides, I think I indicated that I think there is some training needed. And if things aren't clear, perhaps those licensees, their interpretation of the criteria was different than what Dr. Welsh was presenting because three percent versus .03 percent is quite a difference. I think that reflects training, a need for training.

MR. LIETO: I wanted to follow up also on the issue that I think Dr. Guha brought up about the written directive and the timing of when that written directive is completed.

I think there's been a consensus, at least Dr. Hagan got a consensus, that everybody I think here agrees that the criteria should be an activity-based criteria, but I am not sure if there is a consensus on

when that endpoint of that is. Is it when the physician is done implanting or does he actually have to make a final change into the written directive if it is outside the 20 percent?

I think that is part of the things that, one of the things that, is trying to be addressed in the proposed rulemaking, is that very specific issue. But I think it would be very important that either the panel or at least from the workshops that are in progress, that there is a consensus reached as to the timing of when that should occur. Should it be when they are done with the implant before the patient is released from licensee control?

In other words, I think there is a timing factor here, but it is very critical I think as to when, shall we say, the drop-dead moment is for when you start to -- I guess bad terminology --

(Laughter.)

MR. LIETO: -- the last moment at which you can determine when the medical event is going to be assessed. So I think that's one thing that I think needs to be addressed there.

I have a comment about using terminology. I think it was also pointed out it's not what we call it. Okay. It's how we address it. I was pretty much

in agreement to that.

And no offense to Dr. Zanzonico. "Sentinel event" is not, is not, the term you want to use. If anybody has been involved with the Joint Commission, first of all, they have a sentinel event that is defined for radiation events. It's aimed at radiation machines and so forth.

But if you have a sentinel event or use the term "sentinel event" coming out of a Nuclear Regulatory Commission, you are going to be talking about events that are on par with wrong site surgery, amputation of the wrong realm, kidnapping of an infant from a nursery. I don't think we want to go there.

So I think that's one term that we definitely don't want to use. So if you want to come up with different ones, I think that one should be put to bed.

I have a question. It has to do with if we assume that the definition is going to be changed for defining when a medical event occurs as an activity-based criterion and that it's based on the activity at the time the patient is released. Would there still need to be in regulatory space the requirement for a post-dosimetry assessment at some time period?

I don't mean that you wouldn't do that from a clinical standard of care standpoint, but would that even need to be a part of the medical event definition?

FACILITATOR SALTER: Dr. Hagan?

MR. LIETO: And I know it's a clinical question, but to me, I think it's getting into the practice of medicine.

DR. HAGAN: I'll jump in there because there are a couple of comments that may be useful. I think you are right in that the question is whether that post-implant dosimetry needs to be done in regulatory space up until this point has been tied to the potential -- and in some places Wisconsin is an excellent example where absorbed-based metric is being used in regulatory space. And at that point, then you're constrained.

The NUREG, which put out guidelines on how an adequate or an excellent program in brachytherapy and specifically prostate brachytherapy was referred to at times could be organized in order to abide by the regulations and at the same time have a practical program, suggested that a percentage -- these are the regulators, not saying this carried regulatory authority but that what were the design parameters of

a good program so that you could produce high confidence that that program is abiding by the regulations.

And so a requirement that a percentage of procedures would have post-implant dosimetry, that NUREG guidance, which is very helpful, was promulgated before the professional organizations had actually moved to saying that they believed that from a clinical standpoint, each implant should have its own post-implant dosimetry.

So I think the question about whether you should do it now has been largely trumped by the professional organizations, who say "Yes, you should do it on every case." It's still an open issue of whether the regulatory agency would say a program that includes this is a program that provides high confidence, but actually gathering data from the clinical evaluation should be beyond the purview of the regulator.

FACILITATOR SALTER: Dr. Welsh?

DR. WELSH: I might add that although post-implant dosimetry has traditionally been associated with "excellent" programs, nowadays it might be more appropriate to say that if you don't do it, you're not even meeting standards.

So, for that reason, if you don't do post-implant dosimetry, you're not meeting minimum standards anymore in 2011. And, therefore, although it's difficult to see how it might properly fit into regulatory space, I feel that it probably does have a role because of all -- and this is an example of one area wherein the review of the VA event series has caused an alteration of opinion and recommendations.

I personally think that programs should insist on post-implant dosimetry as minimum standards. And if it is not done, it probably is something that is not meeting minimum standards and maybe is in violation, but that's just --

MR. LIETO: I guess the reason I was asking is because if it is from the standpoint of determining what is a medical event, there are a lot of things in the various radiation therapies that are done, both radiopharmaceutical and in seed implant, where there are standards of care and practice that if you're just doing quality care, you are going to do these, but they are not in regulatory space.

From looking for things to being as non-prescriptive as possible, if it's not required in terms of the medical event definition, it might be one thing to be left out, but that's just a comment.

FACILITATOR SALTER: Dr. Ennis? And then Dr. Welsh.

DR. ENNIS: So two comments. So on the current discussion, even if we're having an activity-based definition, if that definition means 20 percent or more of the activity must be within the organ, how is one going to ascertain that without a CT scan, which is what you use for post-implant dosimetry. And to require two CT scans, a regulatory one and then another one, is just a lot of --

MR. LIETO: Well, you're going into the treatment. You've got a plan. You're going to give, say, 100 seeds. All right? You put in 100 seeds. All right? You do your surveys and everything before the patient is released. The patient has got 100 seeds. And the --

DR. ENNIS: So maybe the point to understand is that because of the quality of imaging, the edema, et cetera, it is possible to walk out of the OR thinking you had done what you prescribed and then to find out on your CT scan that seeds are not where you thought they were, you didn't do things properly.

This is what happened in some of the VA cases, for example. Imaging issues lead to -- the

problem, now, these are QA things that need to come to the regulatory bodies. They need to get addressed with the physicians. The program needs to be addressed.

But you cannot tell that without a CT scan or some other highly accurate cross-sectional imaging. You can't just tell based on the ultrasound at the end of the implant. You can't tell in the ultrasound at the end of the implant. So there is no method other than a CT scan. So we shot up one CT scan or some imaging that is both regulatory and clinical post-dosimetric. I don't see a reason to have two, and I don't think you can get away regulatory-wise with none.

In terms of what to call the event, I agree sentinel is really not an ideal. Perhaps recordable, as is being used in New York State or proposed in New York State for lower events in the external beam world, would be the appropriate thing. It would also make the radiation oncologist's life consistent across the external beam or brachy. Most of us do both. So to use different terminology would be awkward. So perhaps a recordable event for both types would make sense.

FACILITATOR SALTER: Dr. Welsh, did you --

DR. WELSH: I think Dr. Ennis has just said it very well and clearly.

FACILITATOR SALTER: Did you have --

MR. LIETO: Just one other comment. I believe Dr. Zelac had brought up the point that the NRC was interested in the dose to other tissues and organs for these brachytherapy seeds implants to determine whether the dose was above or below some type of a yet-to-be-determined metric. And I am wondering, why are we doing it just for seed implants when you don't do it for HDR, you don't do it for external, for iodine-131 or any of the other types of therapy treatments that we use for radionuclides across the board?

I mean, in fact, even since the days of cobalt-60, I mean, you would see. I mean, it wasn't unexpected to see skin effects from the treatment with cobalt-60. Yet, there was never any interest by the NRC to determine what the respective doses were to these other individual organs and tissues from those other various treatments. And invariably you are probably going to find that they would exceed this 50 rem, 50 percent threshold.

So maybe a suggestion from Dr. Welsh's subcommittee of ACMUI. Maybe that is a metric that

needs to be removed from the sub rules.

FACILITATOR SALTER: Dr. Zelac?

DR. ZELAC: I don't agree with the statement that you just made with respect to the doses to other tissues and organs. The fact that it applies to permanent implant brachytherapy is, in fact, simply a carryover from its appearance elsewhere in the regulations.

The same thing would apply for a gamma beam treatment, you know, a gamma knife treatment, for example, or if there were teletherapy to being done for a teletherapy. It's the same regulation. It's simply being applied across the board to all modalities. It's not being simply inserted only for permanent implant brachytherapy.

FACILITATOR SALTER: Anyone else? Dr. Welsh?

DR. WELSH: I might go. Mr. Lieto, are you finished with your questions? I would like to reply to one of your earlier questions or at least comment on it that we heard in one of the presentations from Dr. Dansereau that maybe 1,200 cases were reviewed and approximately 3 percent were found to be medical events.

And this while superficially may seem like

a low number, it's significantly discordant with the Medical Event Subcommittee report, which showed in general 0.03 percent medical events in brachytherapy and 0.3 percent in prostate specifically. 0.3 percent I think is way too high. I think it is way too high because it is a reflection of the inappropriate definition.

So an order of magnitude beyond that is three percent, which is way, way too high. And I think anybody who practices brachytherapy who has three or more medical events a year is going to quickly start to question about whether this is really worth it in the long run after a few years of that.

So I think the point was brought up that if there is a tenfold discrepancy between the states' finding and the subcommittee's findings in terms of medical events, it underscores the fact that maybe there really is an important need for additional training in terms of how to define a medical event because when you look closely, you find that a lot of these very good implants are medical events if you apply the definition very strictly.

Having said that, I think that it would be a mistake to go back and apply the definition very strictly because we will find that yes, maybe three

percent, five percent, or some ridiculous number of our prostate implants would meet the definition of medical event. And that is unnecessary.

FACILITATOR SALTER: Dr. Zelac?

DR. ZELAC: Not to continue on the same line but to go back to one of your earlier questions, which I think, in fact, ought to be addressed by the panel here, you asked about when is the procedure complete?

The current regulation says that the written directive needs to be completed before the completion of the procedure. And that is exactly the problem.

MR. LIETO: Right.

DR. ZELAC: It's indeterminate. It's not specified. So the question comes up when is the procedure complete and what we had intended to do with the proposed regulation was to put in when the procedure was complete, namely before the patient leaves the post-operative recovery room.

MR. LIETO: Does it say before procedure is complete or before administration?

DR. ZELAC: When does a written directive need to be completed?

MR. LIETO: Right. That's right, yes. I

thought they were all said before administration or is it --

DR. ZELAC: No. The current rule says that the written directive needs to be completed before the completion of the procedure. So if the completion of the procedure wasn't by some physician, it is being interpreted as being when the dose was determined, which could be a year later or two years later in some cases.

MR. LIETO: Is that something that could be handled in guidance space, as opposed to regulatory space?

DR. ZELAC: My personal position is that it should be in the regulation because it's not enforceable if it's in the guidance.

FACILITATOR SALTER: Dr. Hagan?

DR. HAGAN: Yes. That specific question is one that's caused a lot of confusion. I agree with Dr. Zelac that we need to have more specific language.

And I would like to make a further comment, modify your definition of the endpoint. I think a number of us have looked at that specific issue as part of the ASTRO task group. It becomes difficult. It sounds logical to start with.

But it becomes difficult to say before the

procedure is complete before the patient leaves the recovery room because there are practitioners where these procedures are performed in the department and imaged directly from the procedure room and brought back to the procedure room without going to recovery.

So to make the definition specific upon the patient's actual presence and recovery from a practical standpoint just doesn't work. But if you modify that slightly to say that the procedure is considered complete when the patient leaves the control of the authorized user or the control of the physician, then we have not identified a practice for which that definition doesn't work. And it maintains the same intent I think with your initial definition.

We are here I think largely because the regulation today is confusing, saying that the revision may occur, a written directive up to completion of procedure, and written for delivery of either temporary sources or sources where the activity can be controlled and the time of delivery can be controlled.

So a one-to-one correlation was that while the completion of the procedure was completion of administration, but for a permanent implant, the dose continues for infinity. So it becomes difficult. It

becomes impossible to tie the completion of the implant with dose delivery. And so with the current regulation, it's confusing.

So I agree with Dr. Zelac wholeheartedly in that we need regulatory language that specifies that in a helpful way.

FACILITATOR SALTER: All right. What I am going to propose is that we take our break. We're a little late, but that's okay. I'm going to say let's take our 15-minute break. So come back at 3:30.

And when we come back, we're going to go take -- we have a couple of questions off the webinar. So we're going to go and hear from some folks on the webinar by reading their question. And then we will hear from Dr. Malmud. Jean St. Germain and Mary Moore, will be the next speakers. If you would still like to sign up to make a comment, just fill out a blue card and let me have it. Thanks.

(Whereupon, the foregoing matter went off the record at 3:13 p.m. and went back on the record at 3:34 p.m.)

**FACILITATOR SALTER: Welcome back. We are going to get started with our second round of public comments. We have a number of speakers. We have some folks on the webinar who wanted to make a comment or ask a question.

Before we get started, I wanted to just give you a quick reminder that insider your packets, there are NRC public meeting feedback forms. There are two forms: one for today and one for tomorrow.

So I just wanted to let you know if you are not coming back tomorrow, please make sure to fill out today's form. Even if you are coming back tomorrow, please make sure to fill out today's form. You can leave it with us here today or you can take it with you and mail it in. But it is very helpful for the NRC to get your feedback on the meetings, how it went, suggestions on how we can do better in the future. So please take some time to fill that out.

What we are going to do now is Gretchen Rivera-Capella over at our webinar station has a couple of comments and a couple of questions from the folks on the webinar. So we would like to go and do that now. And I'm going to turn it over to Gretchen.

MS. RIVERA-CAPELLA: Hi. Yes. The first question or I should say comment is from Zoubir Ouhib

from Boca Raton Regional Hospital. And he is saying that when a physician decides to put more seeds within the prostate, that differs from the intended plan while keeping the same total number of seeds ordered. It only makes sense that change of plan has to be in agreement with the clinical findings; i.e., past pathology report, et cetera. That is the first comment.

The second comment is from Steve Mattmuller. And, actually, I can answer this one for the benefit of everybody. He is asking, are copies of the presentations available to those of us who are, as they say, in the cloud? So the answer for that will be yes. The presentations are going to be available on the public workshops website. And also we can make them available in ADAMS for the public.

The third comment will be from Cheryl Rogers from Wisconsin. And it's a clarification. She's saying that, to clarify, the 1,200 medical events were indeed reviewed by the licensees under their own self-identified criteria to best reflect the authorized users' intent were used to classify medical events. The medical events have been reported. Process improvements have been identified also.

So we have this comment also. And Zoubir

Ouhib again, Boca Raton Regional Hospital, it is giving us another option for the medical event terminology. And he's saying, how about deviation event at different levels, three years or so for another terminology for the medical event?

I have two questions now. The first one will be from Zoubir Ouhib from Boca Raton Regional Hospital. And he's saying that in terms of seed activity, is the panel in favor of having a single unit for activities, such as U, and eliminating millicuries? This could potentially eliminate some of the medical events due to miscommunication between the vendor and the user.

So now we would like you to --

FACILITATOR SALTER: Pose that to the panel. Do you need us to repeat that question? Dr. Welsh?

DR. WELSH: I'll start off by saying that I agree with having a single unit and using source strength, rather than activity. And if we omit the possibility of using millicuries in terms of in favor of air current strength, it might get rid of some of the unnecessary medical events that have occurred, albeit quite rarely, because of the confusion between terminologies. So I'm in favor of it.

FACILITATOR SALTER: Anyone else on the panel? Dr. Mower?

DR. MOWER: I think in my comments that I made this morning, VA supports this position of going to the new units.

FACILITATOR SALTER: Anyone else?

(No response.)

FACILITATOR SALTER: All right. Gretchen, one final question I think we had from someone on the webinar?

MS. RIVERA-CAPELLA: Yes, we do. The last one would be from Alan Jackson from Henry Ford Health System. When the physician is actually performing the procedure, isn't it done in accordance with his or her wishes as long as the correct sources are ordered?

Related is, how do you deal with positional errors? Off by one micrometer is obviously okay, but off by ten centimeters probably isn't. How do you deal with the fact that post-assessment is somewhat fuzzy due to edema, et cetera?

FACILITATOR SALTER: Dr. Hagan?

DR. HAGAN: One comment I would make is that while edema is present whether you are scoring on a source strength-based metric or an absorbed dose metric, the so-called activity metric is much less

sensitive to edema. And so there needs to be a substantial inability to discern margins and to repeat the original PTV before you corrupt the activity metric just apparent in being able to score seeds in or outside of the target volume.

FACILITATOR SALTER: Dr. Welsh?

DR. WELSH: I might add that, although superficially it would seem challenging to have a regulation that would allow a physician to, say, provide an attestation that the seeds were placed in accordance to his or her desires, objectively you do have either a preplan or an inter-operative plan that is generated that does have seed distribution that is designed to provide the dose that the physician intends to provide to the GTV, CTV, or PTV.

If on post-implant dosimetry all the seeds are bunched in one area or they're all in one octant or something bizarre, it would be obvious that that is not in accordance with the physician's plan. So having a physician attest that he or she has placed the seeds in accordance to the desired location is in my opinion still a very reasonable approach. And it is something that can be challenged or validated or refuted because of comparison with the post-implant dosimetry and the treatment plan.

FACILITATOR SALTER: Dr. Zelac?

DR. ZELAC: Simply a follow-on question for Dr. Welsh. Do you think that the attestation alone is sufficient or does it need to be, either through the regulation or some other way, linked to one or the other of the treatment plans, you know, something that is more quantifiable than simply a statement that "This is the way I wanted it"?

DR. WELSH: My reply would be that hopefully this would never happen that you would have an unscrupulous physician who knew that there was something egregiously wrong performed and that they would say, "This is the way I planned it." I think that you could quantitate things by checking the preplan or inter-operative plan on which the seed placement was aimed to achieve and then compare that with the post-implant dosimetry.

And if there is a huge discrepancy that the physician has provided an attestation that these seeds were placed in accordance to my desires, you know something has gone awry.

In most cases, I would suspect that there would be some kind of an explanation or modification to the written directive to explain why the post-implant dosimetry is going to be so very

different.

FACILITATOR SALTER: Dr. Hagan?

DR. HAGAN: Yes. I think a practical way to police this issue is through clinical peer review. And if we are requiring a practitioner to become accredited from ACR, then a clinical peer review process is a requirement for accreditation.

So I would not like to see that requirement also replicated in the regulation, but in terms of regulatory guidance, I think that that would be an absolutely appropriate comment or suggestion for a valid program; that is, that clinical peer review is accomplished in a prescribed manner.

And so ACR, for example, typically requires peer review every six months of the process. And so clinical peer review would pick up the discrepancy between a pre-implant plan and a post-implant evaluation and the discordant operative note or attestation that was associated with it.

FACILITATOR SALTER: All right. Thank you. And thank you, Gretchen. Thanks for everyone participating on the webinar. You can still type in your comments or questions. And we will try to get to those before we finish this afternoon.

We are going to start with the next three

speakers that we have: Dr. Malmud, followed by Mary Moore and Peter Mas. So I would ask Dr. Malmud to come up.

I did want to mention that Jean St. Germain said that her question had been addressed by another member of the audience asking their question. So she is not going to be making a comment.

These are the only three that I have remaining. If you filled out a blue card and I haven't called your name, then I lost it. So just fill out another one and let me know. You can still fill out the cards throughout until about 4:30. I would say then we're going to have to cut it off.

With that, I will turn it over to Dr. Malmud.

DR. MALMUD: Thank you.

First of all, I would like to say that we have been struggling with this issue for a number of years in the ACMUI. I am Leon Malmud. I am professor of radiology at Temple University School of Medicine and Dean Emeritus there. I am currently Chair of the ACMUI.

And, therefore, I have had an opportunity to watch the attitude and approach of NRC to this problem as well as the approach of the clinicians,

both radiation oncologists and physicists, with this issue.

We all have a common goal, which is optimal patient care. And the goal is to reduce the number of errors to zero if humanly possible, though we recognize there will always be a few.

The approach is very different from NRC and from the clinicians, but the goal is the same. NRC is very concerned about proper interpretation of regulations so that they are effective in protecting patients. And, yet, at the same time, do not encumber the therapists with risks that they would like to avoid, unnecessary risks, which, of course, would then result in the limitation of that therapy to the patient.

And, from the physicians, they want the freedom to practice medicine in a way in which they are not encumbered by unnecessary regulations, which do not improve the outcome of care. And, with that, we struggle, all of us together.

Now a couple of comments. The first one is about renaming things. We could call it a bouquet event, but that would not change it. It would neither be a fragment nor felicitous bouquet to anyone who received it. So I wouldn't change the name. I would

just leave it as it is.

I am not aware that dementia precox has been cured by renaming or schizophrenia or that senior Alzheicosis has been cured as yet by renaming it Alzheimer's disease.

There are a few issues that have come up that I would like to comment about. I think we're trying to measure the unknown with the unknown. And that is very risky. We don't know what the incidence is. We truly don't know what the incidence is of complications.

We need a database. Someone has to achieve that database. It will take years to accomplish. It might be ASTRO. The medical body that is entrusted with radiation oncology. And if it can't be, for reasons of expense, then it would have to be the NRC. But we do need a database.

What is a complication? Is a complication merely irradiating some soft tissue next to the prostate beyond what we anticipated it should get or is it a perforation of the urinary bladder or the rectum? Is it a seed that has wandered over the course of two or three years from the prostate into the lung? These things happen. Are they documented? Is it required that they be documented? Is there any

log of these events? I suspect the answer is in some instances no.

So in order to regulate, it is necessary that we know what we are regulating. I remember in medical school, one of the professors in a moment of candor said, "We're not teaching you what we know, what you need to know. We are teaching you what we know." And you will learn a lot more later on. And he proved to be correct.

So the need to regulate is for the protection of the public, but regulating something that is not quantifiable is very difficult, perhaps impossible. So we struggle.

With respect to the issues on the table today, take a look at the prostate. It is a relatively easy organ to look at in terms of one's mind's eyes. But a prostate can have four diseases going on at the same time: benign prostatic hypertrophy, chronic prostatitis, prostate cancer, and perhaps even at STD. And that is the organ that is going to be treated with seeds.

That organ will be varying sizes independently of the treatment with the seeds. And its response to the seeds may be to shrink or it may be to even get larger for a long period of time.

There is no database to tell us what is going to happen. And, therefore, how can we judge the therapist based upon an organ that is changing size for reasons that have nothing to do with the therapy or for reasons that have to do with the therapy but only as an aggravant, not as a cause.

What happens when the seeds are sticking on a string into the bladder? You go to retrieve the one seed in the bladder and pull out a string of seeds. Are they considered seeds that were in the bladder? They may not have been in the bladder. They may have been in the prostate, might they not have been?

Is it fair to make an accusation of all of these seeds being in the bladder when, in fact, they weren't in the bladder? They were in the soft tissue. The same thing may be said of them being in the rectum.

I don't know how often these things happen. I'm not a radiation oncologist. I'm a nuclear physician. But to accuse someone of doing something wrong when we don't know that they were wrong is worse than not to accuse them at all.

It's better to let a guilty man go free than to convict an innocent man. The same thing is

true of a man or a woman who is doing radiation oncology.

So we need to be very certain when someone does something wrong that it was, in fact, wrong.

Where did the 20 percent variance figure come from? I suspect it came from maybe my own committee as a compromise figure, but it has no scientific basis. It's a number. The number could have been 25 percent. It could have been 50 percent.

We know that if the seed is ten centimeters off target, that is a big error. Anybody knows that. A child would know that. All he needs is a little ruler, and you can see that.

On the other hand, if the seed is a few centimeters away, it may or may not have been a bad judgment.

Who keeps records of these? How do we know which therapist did the implants? These kinds of figures should be going on in the hospital. The hospital has a credentialing system. And the hospital recredentials each of us, at least at two-year intervals, and should be keeping those data.

Well, you say, not all physicians practice in hospitals. Some practice in independent freestanding therapy units. But they need to fill out

forms as well. They can judge each other. They may even be in competition with each other, which may make them even more severe judges than we would like.

The point is that we all have colleagues who are our peers and can fill out these ACR cards or the equivalent for us in radiation oncology as we do in nuclear medicine.

My point is that I can raise one issue after another, all of which are proof of the uncertainty of what we are trying to measure. The bottom line is that if we measure these uncertainties too severely, the patient will suffer because the physician and the physicist will no longer be willing to provide the therapy because of the risk of embarrassment.

One of my responsibilities when I was Vice President and Dean of our medical school was to review every negligence case brought against the institution and every one of its physicians. We used to do it on Friday afternoons.

It was such an awful experience for me to see these unfair accusations. Some were fair but the minority. But I asked to move the meetings to Wednesdays because I couldn't finish my week on Friday and go home after listening to this.

We were the institution, you will recall, that was sued successfully by a woman who lost her psychic powers in our CT scanner. If she was psychic, she should have known she was going to lose them.

(Laughter.)

DR. MALMUD: The case was so absurd the university decided to defend it. And it went to a Philadelphia jury. The Philadelphia jury saw a deep pocket and awarded her a million dollars for loss of her psychic powers in our CT scanner. It cost us $100,000 to have the case reversed.

Nevertheless, it is very disturbing to a physician to have her or his reputation smeared for having practiced medicine the best way that he or she could. And that concerns me very much because that will limit the availability of this therapy.

In the last year and a half, I known three individuals personally whom I referred for consultation with prostate cancer who chose not to have seed implantations because of the notoriety in the Philadelphia newspapers about what happened at the VA.

Now, what happened at the VA is not an issue I am going to discuss because I am not a judge, and there may have been guilt there or there may have

been responsibility or there may not have been. We don't know the details.

The point is that that kind of confrontation denies the public, denies the patient the therapy that he or she could benefit from. After all, if there were an ideal therapy for prostate cancer, there would be one remaining. That would be the idea. When we don't have an ideal, we have to use different types of therapy.

So these are uncertainties. There are no certain answers. However, what I would like to see as an outcome is a compromise, at least for the time being, in which we do not penalize physicians or physicists unjustly for uncertainties that are part of the practice of medicine. So we have to deal with the existing regulations and how we come at the issue from the NRC's standpoint.

I've worked with NRC people now for eight years. And I have come to respect very much their intention, their ability, and their intellect, and their willingness to see the other person's perspective. So I think we're working in a reasonable environment with each other.

The current regulations seem to be ones in which most parties would rather measure the activity,

not the dose. Let it be the activity, not the dose. That's what the majority seems to prefer.

As far as the 20 percent is concerned, I would be very reticent to adhere strictly to that number. I don't know what the number should be. Maybe there shouldn't be a number. But there has to be a system in which the innocent are not punished and in which the patient is protected without punishing innocent therapists, who are truly doing the best that they can.

There are certain standards that we know need to be met. I think ASTRO should deal with those. It was shocking to read in the newspaper that therapies could be performed with no follow-up when the standard at the institution, according to the newspaper, was that they should be followed up.

So there needs to be some work done at the local level but not at the NRC level. That's a practice of medicine issue. It should be a practice of medicine issue. But if ASTRO and the radiation oncologists don't want to regulate themselves, the NRC is here and willing to do it on behalf of the public.

But that means we have given up as physicians. And I don't think that we should do that. And I don't think that NRC wants to be bothered with

more than they have to be bothered by if somebody else can do the job as well as they can to their satisfaction.

So those are my comments. They're not questions. They're just statements. But I think the one thing that concerns me in all of this is that if physicians practicing the best medicine they can -- I'm not speaking of those who need to be punished, which the majority doesn't need to be punished. But if physicians practicing the best medicine they can are penalized, even by being harassed and being brought in to defend oneself, is being harassed, -- I can attest to that having watched so many physicians being unjustly accused and sued unsuccessfully -- that we should deal with the issue in a way which we are trying to deal with now, which is establishing reasonable criteria together but not to try and measure the unknown with a known regulation that can apply uniformly. We're better off without the regulation.

Thank you.

FACILITATOR SALTER: Thank you, Dr. Malmud.

If you just want to hold up one second, I will give the panel an opportunity to ask you a

question if they want or for you to respond to anything. Dr. Ennis? And then Dr. Hagan.

DR. ENNIS: I think those were outstanding comments and would only say that ASTRO certainly views its responsibility to help deal with these kinds of issues and certainly welcomes the opportunity to help its members improve their quality of care.

FACILITATOR SALTER: Dr. Hagan?

DR. HAGAN: Yes. Thank you. Thank you for well-thought-through comments. A comment that at the same time is sort of a question to Ron is that, Ron Zelac, if we are in some agreement that a source strength metric may be emerging and that also the use of D90 has been problematic, then in the interim between where we are now and the time that the regulations are rewritten, how do the inspectors go forward? And with what rubric do they continue to do their useful evaluation of the programs?

FACILITATOR SALTER: Dr. Zelac?

DR. ZELAC: In parallel with the activities in which we are currently engaged and which we will be leading towards rulemaking effort, which will include a proposed rule for comment, NRC is also clearly aware of the fact that until that is all accomplished, we will have to be living with the

current rule.

On that basis and because of that fact, NRC has a parallel effort in place as well to the rulemaking. And that is the creation of guidance that will be used by inspectors, available to clinicians to give them an idea of what they should be expecting in the way of regulatory review and action on this matter.

In a preliminary way -- and not to say that this is the final word at all -- there is available on the NRC website as well currently some questions and answers which are to elucidate where we are thinking of being and the direction we are thinking of going.

Those Q&As, as I said, are publicly available. And I cannot give you the website location at the moment, but they are clearly going to be useful, I think both to the practitioners and institutions a swell as to the regulators, until such time as we have revised regulations available.

DR. MALMUD: Thank you, Dr. Zelac.

Now I have to say something. Early in my career, Dr. Zelac and I were at the same institution. And he was in charge of the Radiation Safety Committee. I was submitting one research protocol

after another. And he was rejecting one after another.

(Laughter.)

DR. MALMUD: But he never rejected one without telling me how to correct it. And I knew he would do the same thing today. Thank you.

FACILITATOR SALTER: Thank you.

All right. Our next speaker is Mary Moore. And then after Mary, we have Peter Mas.

MS. MOORE: My name is Mary Moore. I am the radiation safety officer at the Philadelphia VA. And I am also a medical physicist.

I would like to take this opportunity to officially thank on my behalf at least my thanks to the NRC for having these workshops. I think this outreach to the regulated community is exactly what is needed and will help I think stem the blurring that has occurred over the last couple of years between the regulatory community and the clinical community.

We were talking about regulatory space and clinical space and patient space. As Dr. Malmud so eloquently put it, the goal of everyone here is patient safety and optimal patient care. And it's how we go about it that is the issue.

One of the things that I noticed in the

debate where we are talking about D90 versus activity-based metrics, there is a slippery slope with the D90 that has not been addressed. And that is where the regulators become part of a peer review community and participate in peer review with the medical community in order to evaluate whether or not a medical event has occurred.

The regulator, the NRC or the agreement state inspectors, find themselves involved in evaluating a clinical implant and inadvertently become part of the medical team. The lines have been very, very blurred. By recommending a peer review, that the licensee have peer review, a true peer review, not just self-identified cases but all brachy, all external beam, most external bream treatments are done. They have their new patient reviews and their weekly chart checks and what have you.

If there is a peer review of the brachy implants using the standards ASTRO, professional standards AAPM, using those established criteria that are acceptable and are in the realm of the known and continue to develop to identify the unknown, then that should remove the regulator from the possibility of becoming a medical practitioner. It should strengthen the consistency and standards, the application of the

standards, by the medical community. And the communication will evolve as the database is built.

So my comment today is to factor in through recommendation, NUREG if necessary, the regulations that the peer review be the responsibility of the licensee. This is what is done with accreditation programs. It is what the Joint Commission does as well. And it's a proven method that has resulted in improved patient care.

I think that's it. Thank you.

FACILITATOR SALTER: Do we have any comments?

(No response.)

FACILITATOR SALTER: All right. Then I am going to ask Peter Mas to come up. Again, if you would like to make a comment, just let me know by giving me a blue card.

MR. MAS: You always have to do the paperwork first. I'm Peter Mas. I'm from the Hartford Hospital in Connecticut. My role is primarily radiation safety. I'm a medical health physicist by training.

I was listening to the ACMUI Committee members. And I was wondering. There has to be a practice guideline document somewhere. So at

lunchtime I saw you look at the ASTRO guidelines. If I can just take a few minutes to run down a few of these things. They seem to make it quite clear that post-implant dosimetry must be done, that recent studies indicate a post-implant CT and imaging should be at two to six weeks or at day zero or day one after the procedure is completed.

Now, with regards to the written directives, here we run into the trouble where what the standards of ASTRO and ACR might vary from what we are discussing today, a written directive that will tell the intended dose but they don't indicate the volume treated, the use of D90, which we seem to be in agreement that we would rather go to an activity-based system, rather than a dose, D90, or even a volume 100-based target volume prescribing. The other dose parameters they should consider reporting are like rectal doses.

But since I am also involved in doing procedures at the hospital like the cert cases, why don't we establish or would it be possible to establish a maximum dose to other regions type of limitation for these implants so we don't have to be haggling over five millimeters from where the seed lies. We're looking at whether or not the dose to a

volume beyond it might be more than what we establish as an acceptable upper limit.

And, finally, regarding the medical event notion, it was along the same lines. I'm sorry. If we could identify an area where we would be exceeding an intended dose or a dose limit, as opposed to just using the current standard or the rather nebulous current standard that we're trying to apply? That pretty much was just the nature of my comments that we have this document that currently exists.

We as an ACR-accredited institution and JACO-accredited institution seem to want to follow it because we'll be held accountable to that standard should something go awry with one of our implants.

That was all. Thanks so much.

FACILITATOR SALTER: Follow-up comment on that?

(No response.)

FACILITATOR SALTER: All right. What I am going to do right now -- oh, Dr. Welsh?

DR. WELSH: I might just provide a little bit of feedback on some of the points that were brought up. ASTRO has recommended post-implant dosimetry be performed. And ACMUI and I think all of us would concur with that sentiment.

The two to six weeks may be the ideal time to perform that study. I'm not personally sure. But I certainly don't think that a regulator should impose something that may or may not be first considered and discussed and approved by organizations like ASTRO and ACMUI, et cetera. Sixty days may be the appropriate. I'm not 100 percent sure yet. But that's something that is being considered right now.

As far as a maximum dose to other organs, this point has been brought up many times and discussed on several occasions. And I think that a critical point to keep in mind when dealing with prostate brachytherapy, in particular -- and this may be why prostate is different from other forms of brachytherapy -- there are no serial organs radiobiologically in the vicinity of the prostate; whereas, there are parallel organs.

And when we are dealing with the radiobiology of parallel organs, it is probably more appropriate to specify a dose-volume relationship, rather than a single point dose of maximum importance. So those are my comments to some of the questions that you brought up.

FACILITATOR SALTER: Any other comments?

(No response.)

FACILITATOR SALTER: All right. What I am going to do now is we have a statement that came into us that we were asked to enter, to read. And so I am going to do that now.

The statement is from Michael Peters, who is the Director of Legislative and Regulatory Affairs, the American College of Radiology. And his statement is "The American College of Radiology, a professional organization representing 34,000 diagnostic radiologists, radiation oncologists, interventional radiologists, nuclear medicine physicians, and medical physicists, appreciates the opportunity to provide the following statement on the topic of medical events in permanent implant brachytherapy.

"The issue of defining medical events in permanent brachytherapy has been discussed at length by the NRC's Advisory Committee on the Medical Uses of Isotopes in several meetings, reports, and recommendations over the years.

"At its May 2011 meeting, the ACMUI members voted to support the concepts provided to NRC by the American Society for Radiation Oncology. We urge that the deliberations and recommendations of the ACMUI be duly reflected in the language and implementation of the future rule.

"We agree with other stakeholders that a 20 percent deviation of total dose delivered from the prescribed dose is not an appropriate determinant of reportable medical events in permanent brachytherapy. The reasons for this have been thoroughly reviewed in past ACMUI Permanent Brachytherapy Subcommittee discussions and recommendations.

"NRC rulemaking staff should work closely with the ACMUI and other radiation oncology stakeholders to develop an appropriate source strength activity-based metric.

"Due to the complex nature of permanent brachytherapy practice in the real time inter-operative decision-making involved, physicians must be given the flexibility to modify the total source strength administered during the procedure if in their professional judgment a change would result in better care for their patients than the total source strength estimated during the planning and development of the so-called pre-implementation written directive. Thus, NRC should not require that written directives for these procedures be finalized prior to the delivery of care.

"Thank you." So I just wanted to read that in. It came into us. I'm not sure. They

weren't able to be here or participate in the webinar, but they wanted to make sure that that statement was read.

And we do have a little bit more time. And so I am just going to throw out an issue that I heard touched upon, but perhaps we didn't really get into a dialogue on it. There were a couple of different opinions on it. And it's the issue of training to determine medical events.

I heard some folks say it should happen, other folks say it's not necessary. So I would just throw that out as an issue that I think we didn't really discuss fully. So if there's anybody that wants to make a comment on that or, Ron, if you want to clarify anything on that?

DR. ZELAC: A review of medical events that have occurred with respect to permanent implant brachytherapy suggests that in some cases, certainly not all but in some cases, there was not apparently adequate recognition on the part of either the authorized users that were involved, nor the medical physicists that were involved in what constituted a medical event.

What circumstances should result in a report being filed? And it was on that basis that

suggestion had been made that training in medical events, what they are, what the requirements are should become a specific part of the regulation. That's where we are, and that is what the question is.

FACILITATOR SALTER: Dr. Ennis?

DR. ENNIS: I think I'm not sure of the need, although I can certainly see the value when a NUREG comes out. I think with modern technology, it would be possible to do it in a way.

And the key for I think ASTRO would be that it not impose a tremendous burden, both in terms of time or finances on the practitioners already very busy and overwhelmed with regulations, but a short web-based tutorial with documentation that you completed it I think would be an acceptable way to do that and achieve the goals of making sure everyone is aware of the NUREGs.

FACILITATOR SALTER: Dr. Welsh?

DR. WELSH: My personal sentiments are that it is reasonable to have training and education on definition of medical events for precisely the reasons that you have outlined, that sometimes individuals, just through ignorance of the policy, have not identified medical events because of ignorance.

Additionally, if we are going to make changes -- and that is what the purpose of this workshop is -- I think it would be very valuable for people to be educated on those changes that might come from this.

Certainly people who are following this closely, everybody in this room, will make themselves aware of new definitions, but there might be some practitioners who would have difficulty availing themselves of the new rules and regulations.

The question in my mind is not whether this is a good idea. I think it clearly is. But to what extent does it need to be mandated? And what would be the consequences for someone who has not gotten that particular training? That's where I think it steps into some questionable grounds.

And I would like to know perhaps from NRC staff what was in mind for punishment, for lack of a better term, if somebody is not educated on this.

FACILITATOR SALTER: Dr. Zelac?

DR. ZELAC: Yes, yes. I can't say with any certainty, but it appears to me that if there was a requirement for training to be provided and, in fact, there is not evidence that it was provided, that's a violation of the license, the same as if

there's a requirement that a written directive be completed and there isn't a written directive completed, that's a violation.

FACILITATOR SALTER: Dr. Welsh?

DR. WELSH: So then I would have to reply that if it is going to be as stern as a violation, I would probably not be officially endorsing the mandate for training and education. Conceptually I think it is a great idea, but if there is a consequence that's associated with it, I am not necessarily in favor of it any longer.

FACILITATOR SALTER: Any other comments? Dr. Nag? Introduce yourself.

DR. NAG: Subir Nag. Back to this same point about a policeman-like mentality. If you have regulation, you look at the regulation, you start an infringement of this regulation. You weren't driving on the highway at 65 miles per hour. If you were driving at 66 miles per hour, is that a violation? Answer "Yes" or "No"? It is yes. But if you are going to arrest everybody who was going at 66 miles per hour, that would become onerous.

So it's very similar here. Why is it that for years we have been doing permanent implant? There were no problems. Certainly in 2007 or 2008, when the

newspaper came out, you had a huge headline "Botched Therapy at Hospital." And it came out. Everybody who is doing an implant is doing that thing because before that, we were aware that the D90 was not but before long you had the seed into the prostate.

No one was calling it a medical event, but if you applied very strictly the way it was written, it became a medical event. Did that mean all the implants had been bad? No. It was the way the regulations were being interpreted.

The same way I would like to caution the NRC that when you are making the rule, make it in such a way that if you apply relevant theory and I'm sure many inspectors may apply relevant theory, you are not going to get an unintended consequence.

For example, a very obvious example is the rule of 50 percent and 5 rem. That rule, if you are going to apply to every permanent implant done in this country, I can bet you you are going to have about 30 percent, not 0.3, not 0.03, not 3 percent but 30 percent of all the implants done in this country will be labeled as medical events.

So what I am trying to say is apply -- we are making the rules. Of course, it might be possible, but even after that, there will become

unforeseen consequences or unintended consequences. When that happens, apply general common sense when you apply the law.

FACILITATOR SALTER: Thank you.

Ms. Eisner?

MS. EISNER: Yes. I mean, I am definitely in favor of a training, whether the regulations train or not, because there seems to be a lot of confusion concerning what defines a medical event and how to proceed with it.

However, it seems like the perspective has been very punitive. And I'm getting from everyone that, like Dr. Welsh said, certainly it is a good idea. And it is a good idea, especially if there is a change in regulation.

Certainly training should be the standard. And I think if you make it easy for a practitioner to get the training through web-based. I think most practitioners would want to get that type of training, certainly to understand better how, you know, how the regulation was changing and how it impacts how they practice.

So, you know, instead of looking at it as a punitive, perhaps maybe incentive-based the way CMS has been, so pay for performance, you know, maybe

looking at it in a different light because I don't think that it is helpful to the practitioner and it's not helpful to the patient to look at it from the punitive sense. But certainly I think the training needs to be there.

FACILITATOR SALTER: Anyone else?

(No response.)

FACILITATOR SALTER: What I am going to do with about the last 15 minutes is I am going to ask Ron if there were any issues or clarifications or one final question he wanted to pose to the panel. We have about 15 minutes left before we have some closing remarks and just wanted to give you that opportunity.

DR. ZELAC: Well, thank you very much.

There is one thing I would like to ask simply because it hasn't been specifically brought out. And it is important for us as an agency to have input from this panel and the audience on this question.

I think it has been clear so far that the comparison of the result of an implant with what was stated to be the result if not in agreement, should be considered as a medical event. What I am saying specifically is at the conclusion of a procedure, when if we were to go to activity-based, the total source

strength that had been implanted was then entered into the written directive, from our perspective, then, the practitioner, the institution, the licensee is then held to that as what, in fact, had occurred. And if there are differences from that, that, in fact, would constitute an event, whatever you want to call the event.

So what I am basically asking is, do you agree that if the total source strength administered is found to differ by 20 percent or more from the total source strength documented in the post-implantation written directive, then that is an appropriate basis to consider that a medical event has occurred? Do you agree or not agree?

And that is important for us because that is a potential direction that we may be going with this proposed rule.

FACILITATOR SALTER: All right. So let me pose that to the panelists first. And then we'll come out to members of the audience.

(No response.)

FACILITATOR SALTER: Maybe I'll go to the members of the audience first.

MR. LIETO: This is Ralph Lieto. I would just add the phraseology that I think we agreed on at

the time the patient is released from licensing control.

DR. ZELAC: Well, this didn't get into when the post-implantation written directive would be completed, but assuming that there was a requirement and it met that requirement, the question is really if there is now a difference, say, you know, say that a number is stated as this is the amount, this is the total source strength that was implanted in this case. And it turns out later -- and there are a variety of reasons why it could -- why that total source strength that was actually implanted differs from the number that was stated in the written directive by more than 20 percent.

Should that be a medical event? That is the question.

MR. LIETO: When you say "later," I am a little confused. Do you mean that later the patient has not left the treatment room or whatever, right?

DR. ZELAC: It has nothing to do with the patient being wherever. It's simply that it becomes apparent later. And we had an example that very recently a case where there was an implantation and the wrong batch of seeds got chosen, an older batch, rather than the batch that had been intended.

Therefore, the total source strength implanted differed markedly from what the physician had said had been implanted and, in fact, what had been implanted.

MR. LIETO: I understand the situation that you are talking about, but I think in terms --

DR. ZELAC: Later is whenever. It could be a year later, whenever it came to light.

MR. LIETO: Right, but the patient has been released from licensee control.

DR. ZELAC: Right.

MR. LIETO: Okay.

DR. ZELAC: Yes.

MR. LIETO: And that's my point. I mean, the later the time frame of the specific time frame of when later occurs, the patient hasn't left the licensee's control is my point.

DR. ZELAC: Well, clearly if it became evidence that there had been a missed entry into the written directive to complete it, before the patient left the facility, I presume that the licensee would then go to correct that missed entry.

MR. LIETO: Right.

DR. ZELAC: And so the conclusion would be that by the time that patient left --

MR. LIETO: That's why I was asking for --

DR. ZELAC: -- would leave correct.

MR. LIETO: That's why I was asking for the clarification.

DR. ZELAC: Okay.

FACILITATOR SALTER: Dr. Hagan?

DR. HAGAN: My only addition other than agreeing with you and your construct is I think we should look at that figure 20 percent.

MR. LIETO: That's part of the reason I asked the question.

FACILITATOR SALTER: Dr. Ennis?

DR. ENNIS: Just echoing, I think this is the definition that we have been advocating, the 20 percent is arbitrary, as was much more eloquently expressed a short while ago. And some of the data from the VA suggests that that threshold may be slightly too low and 25 percent or so might be a little more appropriate.

It's a little bit of a fine point. I don't know if we want to debate that right now, but I guess we can.

FACILITATOR SALTER: Dr. Welsh?

DR. WELSH: I think right now as the -- if my understanding of the way things are written is correct, there is some ambiguity about what can be

amended in the written directive. And for this to work out ideally, there may be a need for allowing some more substantial adjustments to the written directive based on the intra-operative findings that go beyond the simple adjustments and amendments that are currently allowed.

FACILITATOR SALTER: Dr. Zelac?

DR. ZELAC: I tried, perhaps unsuccessfully, to focus this question on the direction that we are going, where we are going to be with respect to the new rule once it is created, where it is appropriate for us to be going when formulating a re-proposed rule for public comment. So that is what I am seeking, rather than consideration of where we are and what is going on now, where we should be going, what we should be doing in the future.

And so far I have heard that there seems to be agreement that this is a reasonable kind of criterion for declaring some kind of event, whatever you are going to call it. And the only question is whether the 20 percent, plus or minus 20 percent, is a reasonable number to use.

FACILITATOR SALTER: Dr. Nag?

DR. NAG: I think this was agreed upon both in the 2005 Medical Event Subcommittee, 2008

Medical Event Subcommittee, and by ASTRO, by the ASTRO intended panel, that it would be the first implant directive.

And 30 percent was acceptable to us because of lack of any other number. If you want to agree to 25 percent, that would be fine with us, but for the time being, 20 percent of something we decided we could live with.

Oh, by the way, this has to be the source strength and not dose. That was the other question.

DR. ZELAC: Absolutely.

FACILITATOR SALTER: All right. One final call. Comments? Clarifications? Ron, you have a couple of more minutes if there is something else you wanted to raise. Anyone from the audience? Dr. Zelac?

DR. ZELAC: This is the only thing perhaps worth mentioning. After all of this discussion back and forth, we started off this morning with a presentation by myself that went into the history of where we got, how we got to where we are now.

And the first, very first, reference was to a paper that was written in 2005. It went to the Commission. And the reason that paper was written was because the Commission had questioned at that time

whether or not the plus or minus 20 percent that appeared in our regulations as the variance beyond which a medical event needed to be reported was appropriate for all of the different modalities that we regulated.

And there was very careful consideration given by staff to where that number had come from. And it turns out that it was from the ACMUI and whether it remained because it had been put forth a while back, whether it remained as an appropriate number.

The conclusion was that plus or minus 20 percent for all of the modalities -- and this was based on dose variation -- was appropriate with the one exception of permanent implant brachytherapy.

The reasoning behind the original recommendation and why it was considered to remain acceptable is that doses that were greater than 20 percent -- and, again, this is in all modalities -- had at least the potential for resulting in dose to unintended sites that could be of consequence to the patient. And the doses under 20 percent from what had been intended had the potential consequence of not treating the malady appropriately and adequately.

So in both cases, there was potential harm

to the patient. And on this basis and on that basis, then, plus or minus 20 percent remained as a reasonable number.

It probably still is, but for this modality, we're clearly talking about, although it's indeterminate whether 20 percent is really the best place to be, now simply we're talking about total source strength probably, as opposed to dose, as being the appropriate criterion.

FACILITATOR SALTER: Oh, Gretchen is signaling that we have a question from the webinar. This will probably be our final question and comment.

MS. RIVERA-CAPELLA: Yes. This one is from Marleen Moore. And she is saying that from the final example, the one before Ron just said, of 20 percent activity error highlights that what the NRC should be trying to pick up as event are plunders. See also how it's worded for JCO sentinel events. That's what she typed in.

FACILITATOR SALTER: For JCO sentinel events. All right.

WRAP-UP

FACILITATOR SALTER: I think what we are going to do now is we are going to start to close up. Before I hand it over to Mike Fuller for some closing

remarks, I want to thank everyone for respecting the process and each other. It has been a pleasure to work with you today. I hope I see a lot of you here again tomorrow.

I just want to remind you about the feedback forms in your folder. Please take some time to fill those out and let us know what you thought about today's meeting.

We will start again tomorrow in the same location in this room. Registration starts at 7:30. So the rooms will be open at 7:30. And there will be some coffee and continental breakfast. The meeting will start at 8:30. So please make sure you are here and ready to begin at 8:30.

I think they are going to lock this room, but I really wouldn't leave anything in it. You never know. Papers are lying around. They might just get thrown out. So I would encourage you to take everything with you and just bring it back tomorrow.

And, with that, I am going to turn it over to Mike to give us some closing remarks.

MR. FULLER: Thank you, Susan.

I also want to thank all of you who, again, took the time to be with us today. This has been very beneficial to us. And I especially want to

thank our panelists. This has been a very enlightening discussion for me and I think for most of the staff.

On the agenda, it has "Wrap-Up." What I had intended to do this afternoon was to sort of share with you some of the key messages and things that we heard today. Now, there are a number of those that I could point to, but I also notice that on the agenda tomorrow morning I have an opportunity to sort of provide an overview of what we heard today.

So, with your indulgence, what I would like to do is go back this evening and very carefully consider all of my notes so that tomorrow morning I can provide you with the feedback of the things that I heard in a more thoughtful way and so that you will understand what it is that as NRC staff, what were the key messages and the key things that we need to consider as we move forward in the process.

So with that, again, I would like to thank everyone for your time. I guess we'll adjourn at this point. Thank you.

(Whereupon, the foregoing matter was recessed at 4:40 p.m., to be reconvened on Tuesday, June 21, 2012, at 8:30 a.m.)